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Department of Health, Education, and Welfare

Food and Drug Administration

Department of Agriculture

Food Safety and Quality Service

Federal Trade Commission

Bureau of Consumer Protection

Food Labeling; Tentative Positions of Agencies

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Ch. I

DEPARTMENT OF AGRICULTURE

Food Safety and Quality Service

7 CFR Ch. XXVIII; 9 CFR Ch. III

FEDERAL TRADE COMMISSION

Bureau of Consumer Protection

16 CFR CH. I

[Docket No. 78N-0158]

Food Labeling; Tentative Positions of Agencies

AGENCY: Food and Drug Administration, Food Safety and Quality Service, and FTC's Bureau of Consumer Protection.

ACTION: Advanced Notice of Proposed Rulemaking.

SUMMARY: The food and Drug Administration (FDA), the United States Department of Agriculture (USDA), and the staff of the Federal Trade Commission's Bureau of Consumer Protection (FTC) announce their tentative positions on a variety of food labeling issues. The positions are the result of the agencies' analysis and evaluation of written and oral comments received in response to a notice published in the **Federal Register** on June 9, 1978 (43 FR 25296), requesting the public's views on several food labeling issues. The FDA, USDA, and FTC held public hearings across the nation between August and October 1978 to elicit public comments on improving food labeling, and they accepted written submissions until November 10, 1978. These positions also grow out of (1) FDA's Consumer Food Labeling Survey, conducted in autumn 1978 to gather consumers' views on food labeling and (2) the agencies' consideration of these food labeling issues. This notice is intended to prompt further comment from the public about the agencies' tentative positions and other food labeling issues on which the agencies have not yet reached tentative positions. It serves further to announce a public hearing (to be conducted by representatives of FDA, USDA, and FTC) to hear oral testimony on these positions and issues. The hearing will be conducted in accordance with Title 21 of the Code of Federal Regulations, Part 15—Public Hearing Before the Commissioner.

DATES: Public hearing on March 4 and 5, 1980, beginning both days at 9:30 a.m. requests to appear at public hearing by February 22, 1980. Written comments by March 20, 1980.

ADDRESSES: The hearing will be held at the main auditorium of the Department of Commerce, Fourteenth Street and Constitution Avenue NW., Washington, DC.

Written comments to the hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
For Information Concerning the Public Hearing and Scheduling of Presentations: Gary Dykstra, Regulatory Operations Staff (HFC-22), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3470.

For Information on the Technical Aspects of this Notice, :

Taylor Quinn, Bureau of Foods (HFF-300), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20240, 202-245-1057
or
Irwin Fried, Acting Director, Meat and Poultry Standards and Labeling Division, Compliance Program, Food Safety and Quality Service, U.S. Department of Agriculture, Rm. 202, 300 12th St. SW., Washington, D.C. 20250, 202-447-6042.

For Copies of the Documents Described Below and Referred to in this Notice, :

Curtis Noah, Consumer Communications Management Staff (HFJ-10), Office of Policy Coordination, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3170
or
Annie Johnson, Executive Secretariat, Food Safety and Quality Service, U.S. Department of Agriculture, Rm. 3807, South Agriculture Building, Washington, D.C. 20250, 202-447-6735.

SUPPLEMENTARY INFORMATION: This document reports on the comprehensive review, a cooperative venture of the FDA, USDA, and the FTC's Bureau of Consumer Protection, of current food labeling laws and regulations. The proposals it contains result directly from the agencies' commitment to full public participation in the consideration and development of new or revised food labeling laws and regulations; they also result from the first joint effort of the three agencies with responsibility for food labeling and advertising to review the entirety of the food labeling laws and regulations. (Previous efforts, usually initiated by an agency on its own, have been largely ad hoc.)

This document states the agencies' tentative positions on a variety of food labeling issues. In the interest of full public participation, the agencies have decided not to make the positions final until there has been an additional opportunity for public comment. At the same time, however, the agencies will continue to consider (and in some cases to prepare) proposed changes in their food labeling regulations. Thus, the development of regulations to implement many of the tentative positions described here complements the comprehensive review of food labeling laws and regulations.

Unless public comment on this notice presents compelling arguments or substantial new evidence against these tentative proposals, USDA and FDA intend to begin the process of implementing certain of them as soon as possible after the close of the comment period on this notice. After 1½ years of study we find the issues break down into three categories. (Detailed information on the issues is given in the sections titled "Tentative Positions" and "Digest" that appear later in this notice.) The first category is where the issues seem clear, the agencies have authority to act, and there appears to be major need for action. Therefore, it is the intention of USDA and FDA to propose changes in a number of the food labeling regulations, including the following, according to the approximate schedule given below:

Regulation To Be proposed, Expected Publication After Close of Comment Period

USDA

1. To require mandatory percentage labeling for significant ingredients—60 days.
2. To require a statement that ingredients are listed in descending order of predominance—60 days.
3. To require that foods containing 10 percent or more total fat on a dry weight basis declare the specific source of the fat or oil—120 days.
4. To require nutrition labeling—including information on calories, fat, carbohydrate, protein, cholesterol, sugars, sodium and other nutrients of public health concern—on foods about which nutrition claims are made or to which nutrients are added—150 days.
5. To propose serving sizes for various foods—150 days.
6. To require open dating on perishable and semiperishable foods—60 days.

FDA

1. To amend the remaining standards of identity to require declaration of all optional ingredients—60 days.
2. To require a statement that ingredients are listed in descending order of predominance—60 days.
3. To require that foods containing 10 percent or more total fat on a dry weight basis

declare the specific source of the fat or oil—120 days.
4. To require quantitative declaration of total sugars as part of nutrition labeling when the food contains them above a specific level—150 days.
5. To require quantitative declaration of sodium and potassium as part of nutrition labeling—150 days.
6. To define the terms "low cholesterol," "reduced cholesterol," and "cholesterol free"—90 days.

The second category of changes in food labeling regulations that FDA and USDA favor will require changes in legislation. The agencies will propose, therefore, to seek additional legal authority:

1. To require the declaration of mandatory ingredients in standardized foods.
2. To require the declaration of specific spices and colors in all foods.
3. To provide explicit discretionary authority to require the declaration of the specific flavoring used in a product when this declaration is considered necessary for providing important health information (as in the case of a potential allergen).
4. To provide explicit discretionary authority to require quantitative ingredient labeling as part of the ingredient statement.
5. To require nutrition labeling on more foods.
6. To provide explicit discretionary authority to require open date labeling.
7. To provide explicit discretionary authority to control fortification of foods when this control is of public health significance. (FDA is issuing guidelines for fortification entitled "General Principles for the Addition of Nutrients to Foods.")

Finally, there is a category of issues upon which, even after a long period of study and discussion, the agencies have not yet reached tentative positions. In these cases, they are either asking for additional comments or they will act to ensure the adoption of reasonable and sensible positions. These issues include:

1. The labeling of imitation and substitute foods. Here, in the absence of a tenative position, the agencies want comments on a number of options.
2. The format for nutritional labeling. This document outlines the agencies' plan for resolving remaining issues.
3. The information to be required on a nutrition label. Should the present mandatory list of nutrients be retained, expanded, or made more flexible?

The "Food Labeling Tentative Positions" and "Digest" sections more fully discuss these and other food labeling issues.

The following documents, upon which this notice is based, are available upon request and are also on file with the FDA Hearing Clerk and the USDA Docket Room, Food Safety and Quality Service, U.S. Department of Agriculture, Rm. 3805, South Agriculture Building, Washington, DC 20250:

1. Food Labeling: Report on the Analysis of Comments. (The following subordinate material is on file with the FDA Hearing Clerk and the USDA Docket Room:
   a. The June 9, 1978 Federal Register notice announcing the public hearing and requesting comments on various food labeling issues.
   b. The coding booklet describing the categories used in the coding process.
   c. The coding sheet.
   d. A computer printout of total coded data.)
2. Report of the FDA 1978 Consumer Food Labeling Survey.
3. Food Labeling Background Papers.
4. A Review of Adverse Reactions from and Hypersensitivity to Peanut and Tree Nuts (prepared for FDA by the Life Sciences Research Office, Federation of American Societies for Experimental Biology).

Background

In early 1978, FDA, USDA, and FTC[1] agreed that it was time to consider whether the existing food labeling laws and implementing regulations needed to be updated. The Federal laws governing the labeling of food are enforced by the USDA (for meat, poultry, and egg products) and FDA (for all other foods). FTC's interest in food labeling rests upon its responsibility for regulating food advertising.

Congress enacted the Federal food laws in 1906, and although it has revised them occasionally since then, the basic concepts of food labeling have remained unchanged for many years. The last major revision of the food labeling provisions of the Federal Food, Drug, and Cosmetic Act, for example, occurred in 1938. FDA administers this act (hereafter called the FD&C Act) and USDA administers the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act (hereafter called the FMI Act, PPI Act, and EPI Act, respectively).

Since these food laws were enacted, significant changes have occurred in the food industry, in Americans' attitudes toward the food supply, and in their dietary habits. Widespread and rapid advances in food processing and distribution have made a greater variety of foods available to more people. This new technology has so increased the number of processed foods on the market that such products now account for more than half of the American diet; at the same time, a far greater number of Americans eat a substantial number of their meals in restaurants.

The Federal agencies have attempted to anticipate and respond to industry's technological advances and to consumers' demand for increased information about food products through amendments to their labeling regulations. This approach has produced a complex set of food labeling rules that, because of the different statutes FDA and USDA enforce and their different regulatory responsibilities, have sometimes been duplicative or inconsistent. FDA, USDA, and FTC realized the need to pause and assess existing food labeling laws and policies before implementing further regulatory changes. Therefore, the agencies set out to develop an overall labeling strategy that will provide consumers with the information they want and need about today's foods.

To achieve this goal, the agencies reviewed current regulations and solicited the views of the public on various food labeling issues by holding a series of public hearings and by asking for written comments. To supplement this information, FDA sponsored a survey of food shoppers to find out their views on certain aspects of food labeling. In this comprehensive review, the agencies have also attempted to determine how adequately existing food labeling laws and policies meet the needs of today's consumers and they have attempted to eliminate inconsistencies between FDA's and USDA's approaches.

On the basis of the information obtained and their review of current regulatory laws and policies, the agencies have developed tentative positions on various food labeling issues. These positions include proposals for legislation, new and revised regulations, and further research. This document also describes the agencies' food labeling rationale, summarizes the public comments and the results of the food labeling survey, and explains how the agencies reached their tentative conclusions.

Food Labeling Rationale

The purpose of food labeling is to enable consumers to select and use products that meet their individual

[1] All the references to the FTC in this notice refer to the Commission's Bureau of Consumer Protection, whose staff members participated in the public hearings, in the analysis of public comments, and in the preparation of this notice. Although the Commission itself supports this effort, it has not taken a position on the various issues involved, and the views expressed in this document do not necessarily represent the views of the Commission or any individual Commissioner.

needs and preferences. To achieve this purpose, labeling must provide sufficient information to enable the public to identify foods and their characteristics, including their ingredients and nutritional value. Effective labeling, moreover, must also present this information so that consumers can understand and use it in deciding what foods to buy. In their deliberations about recommending specific changes in food labeling requirements to make labels more informative and more easily understood, the agencies have followed the following principles:

1. *Public Health Importance*—Human health depends on good eating habits; effective food labeling can contribute to the nation's health by helping consumers choose foods with the appropriate caloric and nutrient values. Because advances in technology have created more processed and fabricated foods, and because the relationship of nutrition to certain diseases is becoming better understood, accurate and informative labeling about a product's nutrient content and its other characteristics has even greater public health significance now than in the past. Furthermore, disease or other abnormal physiological conditions such as allergies compel many Americans to follow special diets. These people especially need informative food labeling so they can make informed food choices.

In considering each proposal for changing the way foods are labeled, the agencies considered very seriously its public health implications. They are convinced that in those instances when food labeling is the most effective method for providing health protection (the labeling of a food's sodium content, for example) society will find the additional cost acceptable.

2. *The Consumer's Right-to-Know*—Innovations in food processing and packaging have made it increasingly difficult for consumers to judge a product's actual contents from its appearance, even for traditional foods. The agencies have therefore concluded that law or regulation must strengthen those policies that guard consumers' right-to-know about the foods they eat. Acknowledging that food labels play a crucial role in providing the information consumers need to make intelligent choices about foods, and that labels provide a significant educational tool, however, does not mean that food labeling should be either the sole vehicle for educating the public about basic nutrition or the government's only tool for influencing the eating habits of Americans. In short, labeling is only a part of the system that delivers information about food and educates the public about how to choose foods wisely. Responsibility for providing this kind of information and education does not rest with regulatory agencies alone, for many institutions—both public and private—must cooperate to provide the basis for informed choices about food.

3. *Economic protection*—The potential overall economic impact of any proposals to amend Federal food labeling requirements demands careful analysis. Any requirement intended to prevent economic deception or designed to offer savings to consumers, for example, would be counterproductive if the added labeling cost exceeded the projected savings. Determining exactly the relative costs and benefits of specific labeling provisions, however, is difficult—particularly on a national scale. The agencies have concluded, for example, that providing consumers with much of the information—such as declaration of ingredients, identity of the product, and the name of the manufacturer or distributor—essential to saving money on food has relatively little impact on the cost of the packaged product. Percentage ingredient labeling and nutrition labeling, however, may be difficult. Only quantitative labeling can provide the kind of information consumers need to get the most for their money when direct examination does not reveal the food's quality or content, but furnishing a large amount of such labeling information may be costly.

Even where requiring labeling information may, on balance, save consumers money, the requirement may encourage monopolistic practices or make it harder for small businesses to compete. (Requiring certain labeling information that only well-equipped laboratories of large firms could develop, for example, might adversely affect smaller companies.) Although the agencies will attempt to avoid such problems, as a general rule they are convinced that labeling requirements should not change with the size of the manufacturer: if labeling information is necessary for informed decisions about food, it should be provided regardless of the manufacturer's size. Moreover, enforcing a regulation based on the size of the regulated firm would be expensive for USDA and FDA.

The Public Hearings

In the Federal Register of June 9, 1978 (43 FR 25296), FDA, USDA, and FTC announced joint hearings and requested written comments by November 10, 1978, on a series of food labeling topics. The public hearings were held in Wichita, Kansas (August 22–23, 1978); Little Rock, Arkansas (September 18–19, 1978); Washington, D.C. (September 27–29, 1978); San Francisco, California (October 12–14, 1978); and Boston, Massachusetts (October 25–26, 1978). The hearings and the request for written comments were intended to elicit the views of individual consumers about what information they wanted or needed on food labels, and what additional costs, if any, they would be willing to pay for this information.

The agencies sought the public's views on the following topics:

1. Ingredient labeling.
2. Nutrition labeling and other dietary information.
3. Open date labeling.
4. Food fortification.
5. Imitation and other substitute foods.
6. Safe and suitable ingredients.
7. The total food label (as a communication device).

The three agencies made a substantial effort to encourage individual consumers to participate in the hearings or to submit written statements expressing their opinions on improving food labels. More than 2,800 people attended the hearings, and 452 individuals and group representatives testified. The agencies received more than 9,000 written comments.

A team of representatives from FDA, USDA, and FTC reviewed and analyzed the public comments. This group also developed a computerized system for analyzing the public's written comments and oral testimony. The following section summarizes that analysis; more information on the comments on particular issues appears below in the appropriate sections of the "Tentative Positions of Food Labeling." For a detailed analysis and tabulation of the comments, you may consult the final report, "Food Labeling: Report on the Analysis of Comments," on file with the FDA Hearing Clerk and the USDA (FSQS) Docket Room, and available from the FDA Consumer Communications Management Staff and the USDA (FSQS) Executive Secretariat at the addresses given above.

Summary of the Analysis of Oral and Written Comments

The agencies recognize that the testimony received at the hearings and the written comments do not represent a random sample of the American public's views. The testimony and comments came from those who knew of the government's request for consumers' opinions and who were able and motivated to testify or write either for a particular reason or set of reasons (a food-related medical problem, for example) or for an interest in

changing—or perhaps maintaining—existing food labeling policies. Moreover, these views were comparable to the results of FDA's 1978 Consumer Food Labeling Survey, a random survey of American food shoppers.

Nonetheless, the public hearings provided FDA, USDA, and FTC with the opportunity to reach consumers at the "grassroots" level and to hear their opinions on food labeling. It was one of the few times that the three regulatory agencies responsible for food labeling have cooperated to solicit the views of the public in the policy-making process. This process complemented other information-gathering methods such as studies and surveys that are useful in developing public policy.

Few commenters addressed all of the food labeling issues. Most discussed those topics of particular concern to them personally or to the groups they represented, or they addressed specific issues spelled out in the various media releases about the hearings. Thus, while each of the following summary statements represents the opinion of at least a plurality of those commenters who discussed a certain issue or question, that group is only a smaller percentage of the total number of commenters.

A. Ingredient Labeling

Eighty-five percent of all commenters discussed ingredient labeling, making it the most frequently mentioned labeling issue. Most of those who commented on which foods should bear ingredient labeling said that all foods should carry this labeling. the majority further urged that ingredient labeling be precise and easily understood by the average consumer. Nearly half of those who commented on ingredient labeling metioned quantitiative declaration of ingredients, with most favoring percentage listing.

Commenters also asked for more specific labeling information on sugars, salt, fats and oils, spices, and artificial colors and flavors. Those who wanted more ingredient information on food labels often cited a specific health problem as the basis for their request.

B. Nutrition Labeling

Of the 52 percent of all commenters who discussed nutrition information issues, the majority wanted food labels to include nutrition information, and they asked most often for a food's calorie content. Although only a few people commented on whether nutrition labeling should be mandatory as opposed to voluntary, the overwhelming majority of this group wanted a mandatory system. Here, too, commenters said that nutrition labels—and the terms they employ—should be understandable.

C. Open Date Labeling

The majority of the 45 percent of commenters who discussed it favored using an open dating system to some extent; most of those who addressed whether open date labeling should be voluntary or mandatory favored a mandatory system. Commenters emphasized the need to make open date labeling more effective, including an explanation of the date used, storage and handling instructions, and use of an alpha-numeric code (e.g., "Do not use after December 25, 1979").

D. Imitation/Substitute Foods

Almost 19 percent of all commenters expressed concern about imitation and other substitute foods. The majority of those who discussed this issue made general statements about naming or identifying imitation and substitute food products. Some commenters made specific suggestions on how to label substitute foods that are not nutritionally inferior to their traditional counterparts, and some offered their recommendations for labeling substitute foods that are nutritionally inferior to the traditional products they are designed to replace.

Of those commenters who specified what to call a substitute product resembling and intended to substitute for a traditional or standardized food, 75 percent said that such a food should be labeled "imitation." Definitions of the term "imitation" varied: Some thought the word meant nutritionally inferior, and some thought it indicated the food was inferior in some other way. Others said that "imitation" signifies that a substitute food differs in some way from its traditional counterpart or that it does not conform to a standard of identity.

E. Food Fortification

Approximately one commenter in six discussed issues related to food fortification, with most of them giving at least conditional support for the practice. Those who had some reservations about fortification often specified which foods should or should not be candidates for fortification. Other commenters cautioned against over-fortifying foods; some added that only appropriate foods should be fortified, and then only for valid reasons.

F. Quantity of Contents

Approximately 12 percent of the commenters discussed the quantitative declaration of a product's contents; almost all supported some form of weight declaration, and many were concerned about possible deception resulting from the several current quantitative content formats. Of those who supported some form of weight declaration, most expressly requested that labels provide a product's drained weight, particularly for canned fruits and vegetables. Other suggestions included declaring net weight, liquid weight, or fill weight.

G. Costs

Although the majority of commenters asked for additional or improved food labeling information, relatively few (14 percent) considered the economic impact of such changes on food prices. Of those commenters who acknowledged the potential for increased costs, 46 percent said they were willing to pay more, but 31 percent said they were not.

H. Food Standards and Safe and Suitable Ingredients

Food standards and safe and suitable ingredients together attracted remarks from 4 percent of commenters. Of those discussing food standards, 41 percent wanted them eliminated; 28 percent favored continuing the current policy; 23 percent wanted standards applied to more foods; and 9 percent wanted standards applied to fewer foods.

Many of those who opposed the use of standards said they objected to manufacturers not being required to identify all ingredients used in standardized products. Some commenters who favored retaining food standards also said that a standardized product's label should provide more information. Several people specifically mentioned retaining standards for staple foods and developing stricter standards for some foods, such as ice cream.

The majority of commenters who expressed their views on the use of safe and suitable ingredients in standardized foods said FDA's existing safe and suitable policy should be less flexible. Some advocated stricter control over the use of certain ingredients—such as artificial flavors, colors, sweeteners, preservatives, flavor enhancers, and sodium compounds—in standardized foods.

1978 Consumer Food Labeling Survey

To supplement the joint public hearings, FDA sponsored a Consumer Food Labeling Survey, conducted in October and November 1978 by the Response Analysis Corporation, Princeton, New Jersey. The FDA's Bureau of Foods, Division of Consumer Services, later analyzed the responses. The survey included 1,374 personal

interviews with "primary food shoppers," the persons who do most of the food purchasing for a particular household.

To the extent possible, the survey avoided direct questions, such as, "Would you like X information?" because direct questions can lead to results that overestimate the extent of concern. Instead, nearly all survey questions were open ended, allowing consumers to provide their own answers rather than requiring them to select among predetermined alternatives. This type of questioning usually leads to minimum estimates, and in some cases to underestimates, since some individuals may not known about a given type of information or may not think of particular information at the moment of questioning.

A summary of the survey results is presented below. These results can be projected to the national population at an accuracy of plus or minus 3 percent (with a confidence level of 95 percent). The results are divided into four areas: scope of consumer concern with food and food labeling; usage of currently available information; sources of confusion and difficulties with food labels; and consumer desires for food label revision.

Scope of Consumer Concern With Food and Food Labeling

The first question in the survey asked, "Aside from prices, please tell me about any particular problems, difficulties, or concerns which you have with food these days." Forty-nine percent reported no problems other than price. Forty-seven percent, however, mentioned one or more specific problems.

Most of these consumers mentioned problems involving the food itself: 14 percent expressed general concerns about product quality (e.g., food is simply not as "good" as it could be); another 14 percent were concerned about possible adverse health consequences of some food ingredients, and 8 percent said that the food they purchase is not as fresh as it should be.

In addition to concerns about food itself, 8 percent of respondents mentioned specific food labeling problems, and 9 percent mentioned damaged containers, insufficient stock in the store, and similar concerns.

Of the 14 percent of respondents who expressed concern about the health consequences of food ingredients, 35 percent are worried about preservatives, 29 percent are concerned about "additives" or "chemicals" in general, 20 percent are apprehensive about the sugar content of their food, 8 percent expressed concern about artificial colors, 7 percent about salt content, and 4 percent about use of artificial flavors. Only 8 percent of those mentioning the health implications mentioned any problem with the nutritional value of their food.

The survey findings suggest that many American consumers have some degree of apprehension about the safety of their food supply. While relatively few people (about 1 percent of the total surveyed) appear concerned about the nutritional value of food, a large number are concerned about the apparent proliferation of substances that may pose a health risk.

Of the 8 percent who expressed concern about food labeling, 32 percent mentioned the ingredient list, 25 percent mentioned freshness information, 20 percent expressed concern about deceptive or inaccurate labeling, and 19 percent had some concern with the information on the nutrition label (most of these mentioned calorie information).

The second question in the survey was, "Are you satisfied with the kind or amount of information available on food packages and cans?" Consumers who gave negative answers were then asked to state why they were not satisfied.

Fifty-nine percent said they were completely satisfied. Thirty-three percent, however, saw a need for at least some improvement in food labeling.

Twenty percent of those surveyed said the ingredient list could be improved. They most frequently requested the following improvements: listing all ingredients; simplifying the language; providing ingredient information on all products; making the list more legible (e.g., larger print), and listing ingredients by percentages.

Eight percent said nutrition labeling should be improved, and 3 percent wanted open date labeling extended to more products. About 2 percent mentioned a need for drained or fill weight labeling on canned goods. Fewer than 1 percent expressed a desire for information about the specific sources of fats and oils.

Use of Currently Available Information

Consumers were asked what information they looked for on food packages other than product name, brand name, and price. Forty-one percent mentioned the ingredient list. Nutritional information was mentioned by 22 percent, size or quantity information by 18 percent, and open dates by 11 percent. Eleven percent reported not using any label information at all.

When asked directly whether they pay attention to the ingredient information, 77 percent of the consumers surveyed said that they do. This group was then asked whether they use this information to avoid certain ingredients. Seventy-one percent of them, or 54 percent of all those surveyed, responded affirmatively. The ingredients most frequently mentioned were sugars (mentioned most often), salt, fats and oils, and preservatives. Other substances often named were artificial colors, artificial flavors, artificial sweeteners, starches, seasonings, cholesterol, and monosodium glutamate.

When consumers were asked why they avoid these substances, twenty-nine percent of all consumers (53 percent of those who do avoid certain substances) cited a belief that the substances might be harmful or hazardous. Many consumers also mentioned dietary reasons (most often weight control) and personal preferences (tastes and religious reasons). A few people mentioned diabetes, the effects on child health and behavior, or allergy problems as reasons for avoiding the substances.

With regard to the nutrition labeling, 64 percent responded "Yes" to the question "Do you pay attention to the nutrition information?" Most of those who use the nutrition label said they use only part of it; only 6 percent claimed to use the entire nutrition label. According to the survey, consumers look most often for information on calories, followed by information on vitamins, protein, fats, carbohydrates, and minerals, in that order.

Those who reported using nutrition information were asked the direct question, "Assuming that there may not be enough room for all different kinds of nutrition information, would you rather have information about things that people often get too much of (like calories, cholesterol, fat) or things people often get too little of (like protein, vitamins, and minerals)?" By a two-to-one margin (68 percent versus 32 percent) respondents selected information about substances that people often get in excess. (This correlates with survey results showing consumer concerns about possible negative health effects of food.)

On the question of open date labeling, 74 percent reported using dates, when available, to help decide which specific food items to buy. The preferred type of dating (at least for perishable and semiperishable products) appears to be an expiration or "use by" date, which was selected by 40 percent of the respondents. The quality assurance date and the pull or sell-by date were each selected by under 25 percent of the

respondents, and only 15 percent chose pack date.

Sources of Confusion or Difficulty With Food Labels

Consumers were asked, "Do you find any of the information on food packages and cans confusing or difficult to understand?" Twenty-seven percent said they found one or more sources of confusion on labels. (Due to the tendency of survey respondents to be unwilling to admit they are unable to understand something, this response probably underestimates actual problems with current food labeling.)

The most frequently cited problem was the use of technical and chemical names in the ingredient list, noted by a third of those expressing problems with labels. Other sources of confusion were the lack of quantitative information in the ingredient list, the metric system, U.S. RDA's, percentages, other nutrition information, date codes, and the use of small print.

It is also worth noting that at least 23 percent of consumers reported they pay no attention to the list of ingredients, and at least 36 percent reported they do not use the information on the nutrition label. (These respondents were not asked why they do not use this information.)

Consumer Desires for Food Label Revision

Consumers were asked directly whether they would like to have more information, less information, or the same amount now available on food labels. Twenty-five percent said they wanted more information, and only 2 percent said labels already have too much information.

Respondents most often wanted quantified ingredient information. This was followed by requests for simplified ingredient statements and calorie information on all products. There was also interest in greater use of specific ingredient names as opposed to general terms such as "spices." Finally, consumers expressed interest in declarations of sugar content, more open date labeling, declarations of salt content, listing of all preservatives, extending vitamin/mineral information to all products, and listing the ingredients in all products. Interest in declarations of drained or fill weight was relatively low.

In summary, about 10 percent of those surveyed were seriously critical of the current food label and saw a need for significant changes. An additional 15 percent expressed a desire for some changes, but appear less concerned. The remaining 75 percent are divided among those who appear to be satisfied with the food label as it is, are not concerned, or simply find the food label to be confusing for one reason or another.

Based on the information obtained from the survey, the following food label revisions have the highest priority among food shoppers.

Calorie information on all products.
Simplified ingredient names.
Quantitative ingredient listing (preferably in percentages).
Complete listing of all ingredients.
More extensive open date labeling.
Quantitative declarations of sugar content.
Full ingredient labeling for all products.
A simplified nutrition labeling format.
Expiration-type open date labeling for perishables.

The full report of this survey is on file with the FDA Hearing Clerk and the USDA (FSQS) Docket Room. Copies can be obtained from the FDA Consumer Communications Management Staff or the USDA (FSQS) Executive Secretariat. The addresses of these units are provided at the beginning of this document.

Comparison of Public Hearing Comments With Data From the 1978 Consumer Food Labeling Survey

The tables that follow compare the consumer views from the public hearings and the written comments with the responses obtained in the Consumer Food Labeling Survey. The comparison reveals that the concerns expressed by the two groups were often similar. For example, Table A shows that both groups care more about ingredient labeling than ay other general area, and that nutrition labeling is the area of second greatest concern. The main difference between the two groups lies in the level of concern. Even though ingredient labeling is the top concern of both groups, it was mentioned in 85 percent of the hearing comments and in only 20 percent of the survey responses. This pattern is much the same for each table.

The following conclusion can be drawn from the comparison: although the hearing commenters and those who submitted written comments are not statistically representative of the general public, they do reflect the shopping public's concerns about the food label. The higher level of concern exhibited in the hearing and written comments may be due primarily to the fact that these commenters represent a self-selected group with sufficient interest in labeling to submit their views. In contrast, the Food Labeling Survey includes many consumers who do not appear to be concerned about food labeling.

Table A.—*Major Areas of Concern With Food Labels* [1]

	Hearings and comments (percent)	Food labeling survey (percent)	
		Open question [2]	Semidirect question [3]
Ingredient list	85	3	20
Nutrition label	52	2	8
Open dating information	45	2	3
Quantity of contents information	12	1	3

[1] Percentages are based on all respondents in the survey and the commenters in the hearings and written views.
[2] The question titled "open" asked respondents what problems, difficulties, or concerns they have with foods.
[3] The question titled "semi-direct" asked respondents what information on the food label needed improvement.

Table B.—*Label Changes Most Desired* [1]

	Hearings and comments (percent)	Food labeling survey (percent)	
		Open question [2]	Semidirect question [3]
Quantify the ingredient list	35	1	4
Give ingredients of all products	35	1	3
List all ingredients	32	1	5
Give amount of sugar	27	1	2
Give amount of salt	25	1	1
Give nutrition information on all products	10	1	1
Give source of fats and oils	9	1	1
Give drained or fill weights on cans	8	1	2
Use larger print on labels	6	1	2
Simplify the ingredient list	1	1	4

[1] Percentages based on all respondents in the survey and the commenters in the hearings and written views.
[2] The question titled "open" asked respondents what problems, difficulties, or concerns they have with foods.
[3] The question titled "semi-direct" asked respondents what changes or additions they would like on food labels.

Table C.—*Nutrition Information Mentioned as Important* [1]

	In percentage	
	Hearings and comments	Food labeling survey
Calories	62	55
Vitamins/minerals	39	48
Fats	28	32
Cholesterol	24	11
Carbohydrates	22	22
"All nutrition information"	21	9
Protein	20	36
Serving size	10	3
Number of servings	6	1

[1] Percentages are of those who named the types of nutrition information they consider important or valuable.

Table D.—*Substances That Respondents or Commenters Report Avoiding*[1]

	In percentage	
	Hearings and comments	Food labeling survey
Sugar	47	50
Salt	43	26
Artificial colors	33	10
Fats and oils	23	23
Artificial flavors	23	6
"Chemicals"	19	8
Preservatives	17	21
Seasonings	13	5
"Artificial things"	6	18
Starch	2	5
MSG	2	3
Artificial sweeteners	1	6

[1]Percentages are of those individuals who reported avoiding one or more substances.

Table E.—*Preferred Method of Quantifying the Ingredient List*[1]

	In percentage	
	Hearings and comments	Food labeling survey
By percent	85	78
By weight	15	22
Total	100	100

[1]Percentages are of those who specified a preference for percentage versus weight listing.

Table F.—*Preferred System of Open Dating*[1]

	In percentage	
	Hearings and comments	Food labeling survey
Pack date	25	15
Pull (sell-by) date	23	23
Quality assurance (best-if-used-by) date	14	22
Expiration (use-by) date	38	40
Total	100	100

[1]Percentages are of those who specified a preferred dating system. Food Labeling Survey respondents were discussing perishables and semiperishables.

Background Papers

Following the hearings and survey, the agencies developed background papers on each of the key food labeling issues. These papers describe in some detail the questions involved and the options considered by the agencies in arriving at the tentative positions discussed in this notice. While not intended to be an exhaustive review of the subject, the background papers do provide a general overview of the major considerations involved in each food labeling issue. They cover the following areas:

1. Mandatory Ingredients in Standardized Foods and Spices, Flavorings, and Colors.
2. Ingredient Labeling of Restaurant Foods.
3. Ingredient Labeling of Fresh Fruits and Vegetables.
4. Quantitative Ingredient Labeling.
5. Grouping Ingredients by Function and "and/or" Labeling.
6. Mandatory Information in Nutrition Labeling.
7. Nutrition Labeling Format.
8. Sodium and Potassium Labeling.
9. Sugars Labeling.
10. Fiber Labeling.
11. Cholesterol and Fatty Acid Labeling.
12. Composite Data Bases.
13. Serving Sizes.
14. Food Standards—Safe and Suitable.
15. Imitation and Substitute Food Labeling.
16. Open Date Labeling.
17. Country of Origin Labeling.
18. Name and Address of the Manufacturer, Packer, or Distributor Labeling.
19. Natural and Organic Labeling Claims.

These papers are on file with the FDA Hearing Clerk and the FSQS (USDA) Docket Room, and can be obtained from the FDA Consumer Communications Management Staff or the FSQS Executive Secretariat. Addresses are provided at the beginning of this document.

Criteria for Analysis

The agencies used the following criteria in developing the background papers and their tentative conclusions[2]

1. Health Implications:
- What are the risks—allergies, diabetes, high blood pressure, hyperkinesis, heart/circulatory, etc.?
- What is the severity of the risk (high, medium, low); what is the size of the affected population?
- Will improved food labeling assist consumers in eliminating or reducing any known or potential health-related problems associated with foods and food ingredients?

2. Consumer Acceptability:
- What is the public attitude towards the various aspects of the improved food labeling?
- Does it meet the consumer's right-to-know?
- Are consumers capable of using the information?
- Will consumers use the information?

3. Industry Acceptability:
- Will industry accept or oppose the change?
- For what reasons?
- Will the change to require disclosure of it violate "trade secrets"?
- Will the proposed action be feasible to implement?

4. Legal Aspects:
- Does it require a change in the law?
- Does it require a change in existing regulations or a new regulation?
- How does it correspond with our sister agencies? Are there jurisdictional problems? Differences?

5. Political Aspects:
- What will be the reaction from Congress?
- If legislation is required, is Congress in favor and willing to act? Now? In the future?
- How does any proposed action correlate with the Administration's initiative to reduce or eliminate any unnecessary regulations?
- What will be the reaction from the States?

6. Economic Implications:
- Will the information help to prevent economic deception?
- What are the costs to the government to develop, implement, and enforce?
- Will the information help to maximize consumer purchasing power?
- What are the costs to industry to implement? How much?
- Will the label modification cause increased costs to consumers? How much?

7. Efficacy:
- Will the labeling modification actually solve the specific problem it is introduced to address?
- What other methods can be used to meet the same wants or needs (e.g., more consumer education, food formulary, etc.), perhaps at less cost to all segments of society?

8. Timing:
- Is it something that can and should be done now? In the future?
- Is it something that will require a change in law, and thus need to be delayed pending passage of legislation?
- Is it something that can be done now (by regulation) but should be delayed pending further study?
- Is it something for which more specific legislative authority is needed although certain aspects can be implemented by regulations, guidelines, or policy statements?

Tentative Positions

As a result of the information gained from FDA's Consumer Food Labeling Survey, the oral and written comments, and the agencies' review of the issues, the agencies have reached tentative

[2]These criteria are general in nature and the discussion in the background papers does not necessarily completely correlate to every one of the criteria.

positions on a number of food labeling issues. In their deliberations, the agencies considered the views of the public; the feasibility and costs to consumers, government, and industry; and the potential public benefits. These tentative positions are presented in the sections that follow.

Many of the proposed changes will require future regulatory or legislative actions, which are also discussed below. Before any final regulatory actions are taken, the agencies will carefully consider the comments on this document, and each agency will proceed in accordance with the Administrative Procedure Act (5 U.S.C. 551 et seq.) and other legal requirements.

Ingredient Labeling

Ingredient labeling was the issue discussed most frequently by the public at the hearings, in written statements, and in response to FDA's Food Labeling Survey. For example, 85 percent of the commenters in the hearings and their written submissions addressed the topic of ingredient labeling. This is a large issue, with a number of different facets, each of which will be discussed in turn.

Labeling of Mandatory Ingredients in Standardized Foods

In their oral and written statements, the public made it clear they want to know what ingredients are used in foods. Most commenters stated that at least some standardized foods need full ingredient labeling. Many of them simply asked for "full ingredient" labeling on foods.

Several reasons were given for wanting to know all of the ingredients in foods. Some wanted to avoid certain ingredients. Others wanted to be able to identify the presence of specific ingredients for health or medical reasons. Still others said they have the right to know the ingredients in a food. The respondents to the Food Labeling Survey also indicated considerable desire to have ingredients listed for all foods.

Certain Federal regulations called standards of identity, which are established by FDA, define the composition of many foods. The standards identify the mandatory ingredients (which must be used) and the optional ingredients (which may be used). Under the FD&C Act, only optional ingredients in such foods can be required to be declared on the label. If an ingredient is mandatory (e.g., peanuts in peanut butter), it does not have to be listed on the label. FDA has issued about 275 standards of identity. They include standards for canned fruits and vegetables, milk, cheeses, ice cream, breads, and margarine. Standardized foods make up 45 percent of the wholesale value of food shipments regulated by FDA (excluding fresh fruits and vegetables). For a number of years FDA has sought authority to require label declaration of mandatory ingredients in standardized foods but no legislation has passed. (There are two bills now before Congress that would provide this authority: S. 1651 or the "Department of Agriculture Nutrition Labeling and Information Act of 1979" and S. 1652 or the "Nutrition Labeling and Information Amendments of 1979 to the Federal Food, Drug, and Cosmetic Act".)

Foods for which FDA has issued no standard of identity, such as cookies, cakes, and pizza, must have ingredient statements on the label. All ingredients in nonstandardized foods, except for colors, spices, and flavors, must be listed specifically by name in the order of predominance.

Under USDA regulations, the ingredients in meat, poultry, and egg products must be listed on the label in order of predominance. Colors, spices, and flavors may be generally identified, but all other ingredients must be specifically identified. This is true even if the food is subject to a USDA food standard.

In the absence of authority to require the listing of mandatory ingredients, FDA has been expanding the use of its authority with respect to optional ingredients. Most standards have been revised, or are presently being revised, to require declaration of all optional ingredients. Moreover, if two or more forms of a mandatory ingredient may be used, then the form is deemed to be optional and the ingredient must be declared on the label. For example, the flour that goes into bread may be enriched flour, bromated flour, phosphated flour, or a combination of these. Whatever form is used must be declared on the label. FDA has also encouraged industry to list mandatory ingredients voluntarily (21 CFR 101.6), and many manufacturers have complied.

Proposed Actions: FDA will seek or support legislation to amend the FD&C Act to require that mandatory ingredients in standardized foods be declared on product labels. (USDA regulations already require such declarations.)

Pending any such legislative change, FDA will expedite its revision of the remaining standards of identity to require declaration of all optional ingredients including the form of the mandatory ingredients where more than one form is available for use. FDA plans to publish a document within the next year which, when completed, would require declaration of approximately 97 to 98 percent of ingredients used in standardized foods.

Colors, Spices, and Flavors

According to the hearing record and written comments, many people would like to see colors, flavors, and spices listed on labels by their specific names (e.g., "FD&C Yellow No. 5" as opposed to "artificial color"). The desire for specific label information on artificial colors was mentioned most frequently (1,868 commenters), followed by flavors (1,315 commenters), and spices (654 commenters). In addition, 587 commenters discussed the provision in the law which exempts butter, cheese, and ice cream labels from declaring the presence of artificial colors; 91 percent of these commenters wanted this exemption eliminated. The respondents to the Food Labeling Survey also expressed an interest in color, flavor, and spice labeling.

The FD&C Act requires the presence of colors, flavors, and spices to be declared on the label. However, they may be listed simply by their general names ("colors," "spices," or "flavors"). In other words, FDA cannot require specific identification of such ingredients. In the case of cheese, butter, and ice cream, FDA cannot require declaration of even the presence of an artificial color.

USDA has much wider authority in this area. Under current statutes, the Secretary of Agriculture may require that colors, spices, and flavors be identified by their specific names (21 U.S.C. 453(h)(9) and (12); 21 U.S.C. 601(n)(9) and (12) and 21 U.S.C. 1036(a)).

The general position of the agencies is that most ingredients should be declared by specific names on food labels. This position appears to present no significant problems with respect to spices and colors. Most products that include spices contain no more than four or five. (Some meat and poultry products contain a greater number.) The same is true of colors: only a few are used in any one food, and listing them should present no practical problem. Under the provisions of the Fair Packaging and Labeling Act (administered by FDA), cosmetics are now required to list specific colors on their labels, and no serious practical problems have been encountered.

Label declaration of flavors does present a problem, however. There are about 1,700 flavors, and as many as 125 flavors can be used in a single processed food. The average number of flavors used in a processed food (excluding meat, poultry, and egg

products) is about 40. Not only are there numerous flavors, but there are also an overwhelming number of substances that can be combined to form a single flavor ingredient. Since one food may contain many flavors, it would be impractical to identify them fully on the label, and it would be difficult for the government to establish an all-inclusive labeling policy for these ingredients.

Nevertheless, the agencies support label declaration of those flavors that are known to cause health problems, such as allergic reactions in particular segments of the population. This principle was followed in FDA's action to require foods to declare the presence of FD&C Yellow No. 5, a known sensitizer. (See the **Federal Register** of June 26, 1979 (44 FR 37212).) Of course, a flavor (or spice or color) that is unsafe for the general population would be banned from the food supply under current law.

Industry has argued that mandatory disclosure of all colors, flavors, and spices would be an onerous burden because it would overload labels, making them incomprehensible to consumers. Manufacturers also have contended that label declaration of the specific colors, flavors, and spices used in a food will divulge trade secrets.

In the case of colors and spices, the agencies have concluded that labeling specific ingredients would not reveal trade secrets and that the benefits to consumers of knowing the identity of these ingredients would be substantial. Nevertheless, the agencies welcome further comments.

Proposed Actions: (1) Colors and spices. FDA will seek or support legislation to require that all colors and spices be declared on food labels by their specific names. USDA believes it has such authority, but will support legislation to provide more explicit authority for both agencies.

The agencies invite comments from the public on the feasibility of their proposal, particularly for labeling of spices.

FDA will seek or support legislation to eliminate the exemption under which the labels of butter, cheese, and ice cream are not required to declare the presence of an artificial color.

(2) Flavors. FDA will seek or support legislation to provide it with the discretionary authority to require label declaration of a flavor when such declaration is considered necessary to provide important health information, e.g., when a flavor ingredient may cause an allergic reaction. USDA believes it has such authority but will support legislation to provide more explicit authority for both agencies.

Quantitative Ingredient Labeling

The vast majority of the hearing and written comments mentioned ingredient labeling, and nearly half of these had suggestions on how to specify the quantities of ingredients. Of those with suggestions, over 75 percent favored percentage ingredient labeling, 19 percent favored listing ingredients indescending order of predominance, and 6 percent wanted to know percentages of characterizing ingredients (e.g., the shrimp in a shrimp cocktail). The Food Labeling Survey results were similar to the hearing and written comments, thus confirming the strong consumer interest in quantitative ingredient labeling and the preference for percentage listing.

At present, FDA generally does not require quantitative labeling, except for certain valuable and characterizing ingredients that are part of a product's name (e.g., shrimp in shrimp cocktail or orange juice in orange juice beverages). It has been argued that FDA may have across-the-board authority to require quantitative ingredient labeling. But if such authority exists, it is not explicitly stated in the present law.

A more serious limitation may be FDA's inability to monitor quantitative labeling under the present law. FDA could use two approaches to verify quantitative ingredient labeling. The first is by factory inspection. This approach is of limited value at present because manufacturers are not required by law to show FDA their records on what actually goes into a product. The second approach is laboratory analysis. FDA can determine some ingredients by analysis, such as shrimp in shrimp cocktail, but it cannot readily determine others, such as ingredients that may dissolve in a soup. Moreover, analysis can be expensive. Because factory inspection represents the more practical apporach to monitoring, FDA in the past has supported legislation to provide authority to review company records related to production.

Under its statutes, USDA already has some authority to require quantitative ingredient labeling in meat, poultry, and egg products. Moreover, USDA can review product formulas and related information through its mandatory label review and inspection programs. The meat, poultry, and egg product statutes require recordkeeping by processors, and provide access to records and inventory. These provisions make it easier to enforce quantitative ingredient labeling rules. USDA also has issued voluntary guidelines for quantitative ingredient labeling and requires percentage labeling of some products purchased for domestic food assistance programs (e.g., cooked turkey rolls and dried egg mix).

Proposed Actions: FDA and USDA will continue their efforts to encourage or require the use of quantitative ingredient labeling on more foods.

FDA will take the following specific actions:

Expand the use of percentage labeling for valuable and characterizing ingredients as part of the names for standardized foods and nonstandardized foods;

Publish guidelines for voluntary quantitative ingredient labeling as part of the ingredient statement;

Seek or support legislation explicitly giving FDA authority to require quantitative ingredient labeling as part of the ingredient statement;

Seek or support legislation giving FDA records and reports authority: access to a company's product formulas, quality control records, and related records in order to ensure that such expanded quantitative ingredient labeling is truthful and accurate.

While USDA already has limited authority to require quantitative ingredient labeling, it shares FDA's belief that legislation establishing the general authority of the two agencies to require such labeling is desirable. USDA will also propose regulations to provide for more quantitative ingredient labeling. The regulations will propose mandatory percentage labeling of certain important ingredients in meat, poultry, and egg products.

Listing Ingredients by Order of Predominance

The results of the Food Labeling Survey and the hearing and written comments suggest that many consumers may not be aware that ingredients must be listed on food labels in descending order of predominance. Although some labels carry an explanatory message stating that ingredients are listed in order of predominance, there is no requirement that they bear such a message. The agencies believe that an explanatory statement of this type would be helpful to consumers, and would neither prove costly to manufacturers nor overload labels.

Proposed action: FDA and USDA will amend their current regulations to require that food labels bear a statement to the effect that ingredients are listed in descending order of predominance.

Use of "And/Or" Labeling To Declare the Source of Fats and Oils

"And/or" labeling is designed to provide manufacturers with flexibility to modify food ingredients without revising

their labels. Under current regulations, this type of labeling is permitted for fats and oils when they are not the predominant ingredient. A label might bear the statement, "vegetable oil (may contain cottonseed oil, soybean oil and/or palm oil)." The manufacturer would then be free to use any one of the three specific oils, or a combination of them, without changing the labels. The choice would likely depend on availability and price.

The hearing and written comments on ingredient labeling flexibility focused mainly on the declaration of fats and oils. Of the 1,060 commenters who discussed flexible labeling of fats and oils, 86 percent said that the "and/or" type of labeling should not be permitted. Most people opposed this concept due to special diets, allergies, or for religious reasons. Some commenters also expressed dissatisfaction with general source designations such as "animal fat" or "vegetable oil."

About 14 percent of the commenters supported labeling flexibility for fats and oils. Some of these commenters qualified their approval by stating that only those fats with the same saturation should be allowed to be interchanged. Other commenters noted the cost savings to consumers that may result from current rules permitting flexibility.

Respondents in the Food Labeling Survey, on the other hand, showed relatively little concern with this issue; only a very few mentioned labeling flexibility.

FDA's present regulations were published in 1976. Previously, FDA permitted fat and oil ingredients to be declared in the ingredient list by the generic terms "vegetable oil," "animal fat," and "marine oil," or as "shortening," without naming the specific fat, oil, or type of shortening. In 1971 FDA proposed requiring the declaration of fat and/or oil ingredients by specific common or usual names instead of genric names (e.g., "coconut oil" instead of "vegetable oil" or "shortening"). This proposal was made in respense to repeated requests from consumers and consumer organizations, as well as from health professionals.

The 1971 proposal, as well as a revised proposal published in 1974, was opposed by a number of industry members. Opposition was based mainly on two contentions: (1) manufacturing techniques alter fats and oils so that the ingredients in finished form do not differ greatly regardless of source; and (2) requiring more specific ingredient listings would increase food costs because manufacturers would have to reprint labels whenever fat and oil ingredients were changed due to fluctuations in price or supply.

After considering the comments, FDA, in 1976, issued the regulations that are currently in effect (21 CFR 101.4(b)(14)). Under these rules, some flexibility in declaring fats and oils is permitted when these ingredients are not predominant, i.e., when they do not constitute the largest proportion by weight of any ingredient in a food. A manufacturer may declare the blend of fats and oils on the list of ingredients by use of a generic term, followed by a parenthetical listing of the common or usual name of each fat and oil ingredient that might be used in the blend. Therefore, any fat or oil that may be present in the product is specifically identified. Where fats or oils are the predominant ingredient, specific declaration of any fat or oil actually present is required.

USDA currently allows the use of general terms such as "animal fat" or "vegetable oil" on meat and poultry product labels without reference to the specific source of the fat or oil (e.g., cottonseed oil"). The egg product regulations contain no specific references to how fats and oils should be identified, but require that all ingredients be listed if two or more are used (7 CFR 2859.411(c)(1)). However, USDA's policy for egg products labeling allows the labeling of fats and oils on an "and/or" basis consistent with FDA's current requirements.

There appears to be at least one problem with the present system for declaring fats and oils: it may result in the listing of ingredients that are not actually present. As a result, it may narrow the choice of products available to people who wish to avoid certain substances. Thus, although "and/or" labeling does not cause health problems, it does not allow those people suffering from allergies or other medical conditions to deal most effectively with their problems.

The agencies recognize and sympathize with those individuals who may be allergic to the protein fractions in some fats and oils. Although the agencies know this medical problem occurs, they do not know the extent of the problem. The agencies also are aware of religious concerns and personal preferences centering on the use of certain fats and oils. However, even if the use of "and/or" labeling were eliminated, there still would be no guarantee that foods containing more desirable fats and oils would be available. Moreover, the requirement for more specific labeling could impose higher costs on all consumers by restricting manufacturers' ability to respond to marketplace factors (availability and price) without having to change their foods' labels. Finally, if there is a significant need for products containing only a specific fat or oil, the competitive marketplace is likely to make them available (usually at a premium price).

Recognizing public concerns and these economic factors, the agencies have weighed the potential benefits of requiring more specific labeling of fats and oils against the adverse impact such a change could have on industry and consumers.

Proposed Action: FDA and USDA will amend current regulations to require that foods containing 10 percent or more total fat on a dry weight basis declare on their labels the specific source of the fat or oil, e.g., "corn oil" or "palm oil." Foods containing less than 10 percent fat on a dry weight basis may use the "and/or" approach, e.g., "vegetable oil (may contain cottonseed oil, soybean oil and/or palm oil)."

The position adopted by the agencies is based in part on the current FDA regulation covering fatty acid and cholesterol labeling (21 CFR 101.25). This regulation provides that a food containing 10 percent or more fat on a dry weight basis and at least 2 grams fat in an average serving may bear labeling declaring the quantity of fatty acids. A food containing less than this level of fat is not considered to be important in regulating the intake of fatty acids because it is not a significant source of dietary fat.

Use of a 10 percent total fat cutoff level would result in the listing of specific fats and oils on the labels of a substantial number of foods that now bear "and/or" labeling. For example, most crackers, cookies, imitation meats and cheeses would no longer be able to use "and/or" labeling.

The agencies are not aware of any data suggesting that the demarcation line should be higher than 10 percent total fat on a dry weight basis. In fact, it is possible that a lower level (e.g., 2 percent or 5 percent) may be more appropriate. The agencies welcome comments on alternative percentage cutoff levels. Economic data on the effects of various levels on the marketplace will be particularly helpful. Comments are also invited on the question of whether "not less than 2 grams of fat in an average serving," the second part of the present standard for the fatty acid declaration, should be used in conjunction with the 10 percent level as the cutoff for listing fats and oils specifically, or whether some other serving quantity and percentage cutoff should be used.

Functions and Names of Ingredients

The hearing record and written comments suggest that many people find many ingredient names confusing and meaningless. Comments differed, however, on the type of labeling terminology considered most useful. Of the more than 1,000 commenters specifying the terminology that should be used, over half the suggestions favored individual, familiar names, while a third of them favored designation by function, e.g., emulsifier, preservative. Twenty-seven percent supported the use of an ingredient's chemical name on the label. The central point that emerges from the comments is this: as the number of processed foods and the number of unfamiliar ingredients in these foods has grown, the task of interpreting names of ingredients and their functions has become extremely difficult for many consumers.

The FD&C Act requires that optional ingredients in standardized foods, and all ingredients in nonstandardized foods, be declared on the label by their common or usual names ("nonfat dry milk," "celery," "enriched flour"). The exceptions are spices, flavors, and colors, which may be listed on labels by their general names (e.g., "spices"). A limited number of dairy, egg, and oil ingredients are exempt from the specific name requirement and may be designated collectively on labels (e.g., "whey" can be listed when it is reconstituted whey).

Much of the present confusion over ingredient listing may stem from lack of knowledge among consumers of the purposes served by many ingredients. The agencies have received suggestions that the government publish a list of all food ingredients and their functions. This publication might be made available to consumers through outlets such as supermarkets, libraries, etc. Consumers with questions about ingredients would be able to consult this "ingredient dictionary."

Proposed Action: The agencies will explore the feasibility of an "ingredient dictionary." They will determine how it should be compiled and distributed, and what it will cost.

An ingredient dictionary would satisfy the needs of consumers who want to know more about the function of different ingredients, and would not increase manufacturers' labeling costs or overload product labels with complex terminology and explanations.

Labeling of Fresh Fruits and Vegetables

Less than 2 percent of the hearing and written comments requested information on the growing, processing, and handling of fresh fruits and vegetables. Most of these comments concerned the use of fertilizers, pesticides, and other chemicals during growth, and the use of waxes, colors, and gasses.

Under the FD&C Act and FDA regulations, all ingredients added to raw agricultural products, except pesticides, must be declared in labeling (21 U.S.C. 343). If these commodities are shipped in a bulk container and the product is sold at retail from that container, the declaration must be visible to the purchaser. If the raw commodities are sold from a container other than the shipping box, then placards or signs must be used to convey information on colors, preservatives, and waxes (21 CFR 101.22(e) and (f)).

Although the Federal law requires labeling declarations at the retail level of substances added to fesh fruits and vegetables, as a practical matter FDA does not have the resources to enforce this requirement. The agency focuses its compliance attention on manufacturers, processors, and distributors. Retailers, nevertheless, have a responsibility to comply with the law.

If current law or regulations were amended to require the labeling of fertilizers and pesticides used on fresh produce, FDA's lack of compliance resoures would prevent the agency from enforcing such requirements. Even with adequate resources, enforcement would be difficult. For example, pesticides may be present in such small amounts that they cannot be readily detected. In fact, pesticide may be applied to a commodity and not be present at all when the product is marketed. Finally, the fact that fresh produce sold at retail usually consists of mixed lots makes accurate pesticide labeling virtually impossible.

Proposed Action: FDA will continue to encourage compliance with the requirements of Federal law that the presence of colors, preservatives, and waxes be declared on placards and leaflets at the point of sale of fresh fruits and vegetables. however, FDA will not seek the statutory authority to impose similar requirements for pesticides and fertilizers. The policy with regard to pesticides and fertilizers wil be reexamined in the future as necessary.

Ingredient Labeling for Restaurant-Served Foods

Very few commenters (76) discussed the issue of ingredient labeling for restaurant foods. All but one of these commenters said that restaurants should provide ingredient information on their foods.

Although the agencies can understand why some consumers want ingredient information about restaurant-served foods, enforcing such a requirement in the more than 350,000 restaurants in the United States would not be feasible. Not only is there a multitude of ingredients in each food on a menu, but many restaurants also vary menus frequently or change recipes according to the availability of raw commodities. Ingredient labeling would increase cost for restaurateurs, and be a particularly burdensome requirement for small restaurant operators. These costs ultimately would be passed on the restaurant customers.

State and local governments have primary authority over eating establishments. The Federal agencies considered preparing a model code for restaurant ingredient labeling, similar to the Food Service Model Code, for States to adopt. The agencies have concluded, however, that the costs involved in developing such a code outweigh the potential benefits to consumers.

The agencies, of course, support the efforts of many State and local authorities to provide accurate descriptions of restaurant-served foods.

Proposed Action: The agencies will not at this time initiate any action to require that ingredients in restaurant-served foods be declared. This policy will be reexamined in the future as necessary.

Incidental/Secondary Ingredients

A few (118) commenters said they wanted information on ingredients, such as adhesives, that may migrate from packaging materials (incidental or indirect additives) and ingredients, such as calcium silicate in salt used in making bread, that may be components of ingredients used in manufacturing a finished food (secondary ingredients).

Under the FD&C Act, FDA requires that optional ingredients in standardized foods and, with few exceptions, all ingredients in nonstandardized foods be declared on labels. Current FDA regulations (21 CFR 101.100(a)(3)), however, exempt incidental food additives from the statutory labeling requirements. "Incidental additives" are defined by this FDA rule as those substances that are present in a food at insignificant levels and that do not have any technical or functional effect in that food. USDA follows the same general policy.

FDA, USDA, and FTC have considered requiring that such potential additives be declared on food labels. However, the possible presence of incidental additives is not believed to be of any public health significance. Their

presence in food is not always predictable, and even so, their safety is fully assessed. The agencies have concluded, therefore, that such a requirement would not be necessary, and may not be practical or worthwhile. It would require analysis of food lots for potential incidental additives between harvest or manufacture and consumption. Conducting screening analyses for possible additives would be extremely difficult and costly for both government and industry, and the costs ultimately would be passed on to consumers, with little or no benefit obtained.

Proposed Action: The current policy of not requiring the declaration of incidental/secondary ingredients will be continued. This policy will be reexamined in the future as found necessary.

Nutrition Labeling

Nutrition labeling figured prominently in the White House Conference on Food, Nutrition, and Health held in late 1969; nutritionally labeled foods began appearing in grocery stores 4 years later, and they are now quite common.

Even though nutrition labeling is relatively new, the public response it generated was second only to that of ingredient labeling: 52 percent of the commenters discussed some aspect of nutrition labeling, and 3,288 commenters said they want nutrition information on food labels. Those favoring nutrition labeling said they wanted "all" nutrition information to appear on labels, and the rest discussed specific features of nutrition labeling that particularly concerned them. They most frequently mentioned processed or packaged foods as specific food category needing this labeling.

Three main questions characterize this issue: (1) Should nutrition labeling be required on foods? (2) If so, what information should it furnish? (3) Finally, what form should that information take?

Mandatory, Discretionary or Voluntary Nutrition Labeling

This issue concerns whether the government's current, primarily voluntary nutrition labeling policy should be changed either to make nutrition labeling mandatory or to provide FDA and USDA with the authority to require nutrition labeling at their discretion. Much food, of course, already carries nutrition labeling. An FDA survey based on 1976 sales showed that, on a dollar basis, approximately 40 percent of all packaged processed foods and 24 percent of all foods in supermarkets carried nutrition labeling, and that 60 percent of foods with nutrition declarations were labeled voluntarily.

Under FDA regulations (21 CFR 101.9), a food label is not required to bear nutrition information unless (1) a manufacturer makes a nutrition claim about that product on its label or in its advertising or (2) a producer adds nutrients to the food. These FDA regulations define how nutrient content must be disclosed when nutrition labeling is used on a food. USDA does not have nutrition labeling regulations for meat and poultry products, but it accepts and uses FDA's approach on a voluntary basis, and also allows the use of an abbreviated format. Egg product regulations, however, do require nutrition labeling when nutrients have been added to the product or when a nutritional claim is presented on the label, unless the product is specifically exempted. Otherwise, nutrition labeling for egg products is also voluntary (7 CFR 2859.411(e)).

Of the 855 comments on this issue, 88 percent favored a mandatory system. A few commenters suggested that mandatory nutrition labeling should apply only to specific products such as (1) foods that are fortified or for which nutrition claims are made, (2) processed foods, and (3) foods produced by companies with a business volume of more than $500,000 annually per product, but the public preference for mandatory nutrition labeling is clear.

It is less clear whether FDA and USDA have authority to go further to require nutrition labeling on all food products.

Proposed Actions: FDA and USDA will seek or support legislation to clarify their authority to require nutrition labeling on all foods.

USDA will propose regulations that would require nutrition labeling where nutrition claims are made for a product or where certain nutrients have been added to the product.

The three agencies also are forming a task group to develop criteria for determining which additional foods should bear nutrition labeling. The criteria will primarily reflect (a) the significance of the food in the diet; (b) the potential for misleading the public when a food does not have nutrition labeling; and (c) other matters of public health significance.

The agencies invite public comment on these criteria, or others, and their task group will consider these comments in developing the criteria—a task they expect will take 4 months from the close of the comment period.

Nutrition Labeling Format

FDA's regulations on nutrition information (21 CFR 101.9), in effect for over 5 years, provide that if a food's label bears nutrition information, then the data must be accurate and must follow FDA's prescribed format. However, the public has long been interested in improving the format for presenting nutrition information, and industry has considered experimenting with alternative formats.

The 416 commenters on this issue were divided on the type of nutrition label format that would be the most useful. The most popular format was some form of a pictorial/graphic system. Other suggestions included the present FDA system, a rating system, nutrition scores, nutrient density, and food group systems. One hundred seventy of the 195 commenters who expressed their views on the comprehensibility of current nutrition labeling said that some aspect of this labeling puzzles them, and they indentified the U.S. Recommended Daily Allowances (U.S. RDA) most often as the primary source of confusion.

Similar points were made in FDA's Consumer Food Labeling Survey. Twenty-three percent of those surveyed who use nutrition labeling information said they find some aspects of the label confusing, and they identified the confusing elements as terminology (79 percent), use of the metric system (27 percent), use of "big words" (16 percent), use of U.S. RDA's and percentages (15 percent), and not knowing how to use this information (8 percent).

The agencies have concluded that the current nutrition labeling system, a good first step, needs revising to make it more useful to consumers. However, there is a lack of consensus and research on what types of changes should be made.

Proposed Actions: The agencies, therefore, propose to retain the present nutrition labeling system pending the outcome of research to determine which format consumers find most useful and convenient and what changes, if any, are appropriate. The agencies will encourage and facilitate voluntary experimentation, by industry, with graphic and other formats that are consistent with the principles of the current quantitative system, or with new concepts that this research produces. Such studies are to be carried out under carefully controlled conditions and in collaboration with FDA and USDA. The agencies will establish an interagency task group to work with industry and consumers to develop proper experimental designs and the

appropriate criteria for evaluating these experiments.

FDA will participate in the research and experiments by studying various labeling formats, including those formats suggested during the hearings and in the written submissions, to determine which ones best convey nutrition information to consumers. USDA will cooperate fully in, and, if necessary, supplement this research, which the agencies expect to continue for 2 years. (The "Total Food Label" section below provides more information on this research program.)

The interagency task group will complement this research program. It will ensure close collaboration among the agencies, it will hold open meetings frequently, and it will invite full participation by both industry and consumers. The agencies hope that, as a result of the task group's efforts, industry will voluntarily undertake some pilot programs to test—under real market conditions—the proposed new label formats. The agencies will collect data from these pilot programs; the task group which will start working immediately after the next public hearings, will analyze and evaluate this research, and will invite comments and participation during this process before selecting no more than two or three alternative label formats for nationwide use. It will select label formats upon which some pilot programs could be based by November 1980 and will begin evaluating these pilot programs a year later. The agencies welcome comment on the role and functions of the task group.

Mandatory Information for Nutrition Labeling

This issue involves two questions: Should the government change the list of nutrients that must be declared on nutrition labels? Should nutrients present only in small quantities be declared on food labels?

Current rules require nutrition labeling of FDA-regulated products only when nutrients are added to a food or when nutrition claims are made in its labeling or advertising. 21 CFR 101.9, however, requires any FDA-regulated product that bears nutrition labeling to declare the serving size, number of servings in the container, and number of calories in a serving; the quantity of the macronutrients (protein, carbohydrates, and fat) expressed in grams in a serving; and eight nutrients (protein, vitamin A, vitamin C, thiamine, riboflavin, niacin, calcium, and iron) expressed as percentages of the U.S. RDA. Declaring quantities of any or all of 12 additional vitamins and minerals (vitamin D, vitamin E, vitamin B_6, vitamin B_{12}, folic acid, phosphorus, iodine, magnesium, zinc, copper, biotin, and pantothenic acid) and mentioning other nutritional characteristics are voluntary.

The only specific USDA regulations requiring nutrition labeling apply to certain egg products, but producers of meat, poultry, and egg products may voluntarily provide nutrition labeling. In the absence of regulations, USDA uses the same nutrition labeling format as FDA, and it further accepts, in the case of meat and poultry products, an abbreviated format consisting of the macronutrients (protein, fat, and carbohydrates) and calories. (Approximately 75 companies now use nutrition labeling for about 275 different meat and poultry products USDA regulates; luncheon meats, pizza, and canned foods most frequently bear this labeling.)

Evidence from the hearings, the written comments, and FDA's Food Labeling Survey suggests that the public is most interested in the information that appears at the top of nutrition labels: calories, fat, carbohydrates, and protein. The 3,450 commenters who specified what nutrition information they consider important identified calorie content most often, but they also said that cholesterol content, carbohydrate content, protein content, and vitamin/mineral content were important. Only 6 percent of those polled in the FDA Food Labeling Survey claimed using the entire nutrition label. These comments show that some consumers do not use much of the nutrition information currently available, and, when they do, generally find only one or two facts useful. These results suggest at least two possibilities: labels currently contain too much information, or consumers do not know how to use what is there. Accepting the second possibility would further suggest the need for providing more information about nutrition labeling and education on how to use it.

The response also raises a number of very important basic issues involving mandatory nutrition labeling. The public's extensive interest in caloric content undoubtedly reflects the weight consciousness of the American people. Accordingly, the agencies considered allowing a calorie declaration in the absence of full nutrition labeling. They concluded, however, that because it would fail to provide a balanced presentation of foods' nutrition characteristics, this would be inappropriate as a general rule. Industry is producing—and people are eating—more low-calorie foods, but this trend does not diminish the body's need for an adequate supply of vitamins, minerals, and other nutrients. Calorie information by itself generally does not provide adequate information for making sound dietary decisions: The agencies agree that nutrition labeling should usually provide a general nutrient profile of the food.

The views expressed on mandatory information also raise interesting questions about how much flexibility the government's policy should allow. Some have argued that declaring vitamin and mineral content on all nutrition labels is unnecessary because consumers use this information less often and consider it less important. Some said that because most nutrition labeling is voluntary, a requirement for an extensive list of food components on labels could actually discourage use of nutrition labeling. Others, however, emphasized the importance of a more complete nutrient profile to inform consumers of food characteristics having possible public health significance.

Part of this question involves the declaration of mandatory nutrients available in small quantities (less than 2 percent of the U.S. RDA per serving). Currently, nutrients present in such small amounts must be listed as providing "zero" percent of the U.S. RDA or identified by a statement that the product contains less than 2 percent of the U.S. RDA of the nutrient—a policy that reflects the principle that declaring what is not in the food can sometimes be as important as declaring what is in it. Moreover, increasing concern about the adequacy of the amounts of certain micronutrients such as zinc, folic acid, and copper in many diets gives greater urgency to the question of mandatory or voluntary declaration of these nutrients.

Proposed Actions: FDA will continue its current policies for declaring mandatory nutrients (protein, carbohydrates, fat, and certain vitamins and minerals), calories, and other information pertaining to serving size and servings per container.

USDA will continue to permit use of both the format similar to FDA's and the abbreviated format consisting of macronutrients, calories, and other information deemed useful to consumers. USDA will also propose nutrition labeling regulations to provide information on calories, carbohydrates, protein, fat, sugars, cholesterol, sodium, and other nutrients of public health concern.

The data from the FDA survey, hearings, and written comments—as well as those from other sources—suggest that a review of the information in current nutrition labeling is appropriate. Accordingly, the agencies

invite aspecific comments from the public on the following questions:

(1) Should they retain the present mandatory listing, or should they expand it to include certain other micronutrients such as folic acid, copper, and zinc?

(2) Should they make it more flexible to allow for declaration of certain nutrients on an optional basis? (For example: Should they require only that a nutrition label list serving size, servings-per-container, calories, protein, fat, and carbohydrates? Should a listing of a food's vitamin/mineral content be optional when no nutrition claims are made and no vitamins or minerals are added?)

(3) Should nutrition labeling mention a nutrient when one serving of the food provides less than 2 percent of a U.S. RDA?

Composite Data Base for Use in Nutrition Labeling

The issue here is whether FDA and USDA should continue to require food manufacturers and producers to insure that their food labels accurately reflect the nutrient composition of their products, principally by analyzing individual lots of products, or whether they should allow manufacturers and producers to shift to the composite data base concept for deriving appropriate nutrient values for labeling.

Although FDA's Consumer Food Labeling Survey and the hearings and written comments showed that consumers want nutrition labeling on more foods, only 53 commenters discussed what degree of accuracy should be required in nutrition labeling. Most of those said they preferred the statement of nutrient content by an "exact value"; others said that "representative values" or a "range of values" would be acceptable degrees of accuracy.

The current policy of FDA and USDA assigns each manufacturer the responsibility for assuring the validity of a product's stated nutrient values. A number of firms have complained that the required nutrient analyses are expensive, and they argued for a data base to help them determine the nutrition values to be declared on their products' labels. Such a data base would be compiled for common use by food processors who would then not have to carry out nutrient analyses on their products as often as they now do. The net result of such an approach, the argument runs, would be an increase in the number foods bearing nutrition labeling. The agencies agree that nutrition labeling on more foods is the goal, but they also agree that having more information is scarcely helpful if that information is inaccurate.

Much attention has focused on the National Nutrient Data Bank maintained by USDA and on USDA Handbook 8, used for deriving appropriate nutrient values for nutrition labeling. Smaller segments of the food industry, producers of fresh or minimally processed foods, and (to a lesser extent) all food processors would presumably benefit from a change in current policy. Although the agencies agree that a current valid composite data base would be acceptable, the data available for some foods are inadequate for nutrition labeling.

Proposed Actions: FDA and USDA will maintain for now the current policy that products be labeled according to compositon, and that the manufacturer is responsible for insuring the validity of nutrient content expressed on the food label.

FDA and USDA agree, however, that as reliable data bases are developed, they will be suitable for helping determine the values to be declared on many foods. The agencies strongly support the development and use of modern data bases for nutrition labeling, and their inclusion in the National Nutrient Data Bank. USDA and industry are working to improve these data bases and to bring them up to date; FDA has also been assisting in the developing of data bases for nutrition labeling. This work is progressing: the dairy orange juice, fresh potato, and potato chip/snack food industries, to name a few, have already developed useful data bases.

To clarify their position and to encourage further work, USDA and FDA have prepared the following statement setting forth their policies on nutrient data bases:

Statement of Policy Concerning the Use of Nutrient Data Bases

FDA and USDA encourage industry to develop and maintain meaningful data bases that may be useful guides for determining the nutrient vlaues of indigenous nutrients.

FDA and USDA likewise encourage industry to submit such data bases to them so that they may judge their applicability for use in nutrition labeling. The sampling plans and statistical factors to be used in developing the accuracy of the nutrient profile appearing on the label will be determined, according to the food and the nutrient, for each data base. This evaluation will not constitute approval, but it will assist industry in developing and interpreting a data base for nutrition labeling.

FDA and USDA encourage the use of properly evaluated data bases for all appropriate segments of industry.

The use of a suitable nutrient data base does not exempt a manufacturer from assuring that a product meets its labeled nutrient content within established limits. The agencies consider this provision necessary to ensure proper handling of foods and their proper processing to prevent gross nutrient loss (loss of unstable nutrients, for example). The establishment of reasonable ranges of nutrients to accommodate natural variation is under consideration.

If products bearing nutrition labeling in accordance with properly evaluated nutrient data bases and manufactured in accordance with good manufacturing practices are found not to be in compliance with applicable nutrition labeling regulations, the agencies will work with the firms responsible for the product in question and with the appropriate authorities who are maintaining the applicable nutrient data base to correct the problem before initiating compliance provisions actions. The agencies will continue to reexamine compliance of the nutrition labeling regulations and will consider appropriate revisions as new knowledge, data, and methodology become available.

Industry should submit the data base information it develops to the National Nutrient Data Bank.

Serving Sizes

FDA regulations (21 CFR 101.9(b)(1)) define "serving size" as "that reasonable quantity of food suited for or practicable of consumption a part of a meal by an adult male engaged in light physical activity, or by an infant or child under 4 years of age when the article purports or is represented to be for consumption by an infant or child under 4 years of age." Serving size plays a crucial role in nutrition labeling, because the nutrient information is declared in relation to the average or usual serving or portion consumed. The question here is whether the agencies should standardize serving sizes.

In 1974, FDA proposed setting reasonable and uniform serving sizes for certain products, including fluid milk beverages, noncarbonated breakfast beverages, hot and ready-to-eat cereals, and formulated meal replacements. FDA also asked for information in order to set appropriate serving sizes for canned tuna and canned and frozen fruits and vegetables. FDA announced its intention to establish reasonable serving sizes for other foods if industry failed to petition to establish them. Since then, FDA has

proposed serving sizes for soft drinks, and some industry groups have submitted petitions to set serving sizes or portions for other foods. FDA has taken no final action on any of these petitions, and USDA has not yet established a serving size regulation.

FDA and USDA believe that some serving sizes currently used on labels are not reasonable or uniform within a product class, and consumers have expressed similar views. For example, some manufacturers use overly large serving sizes to inflate the nutritional value of their products; others keep serving sizes rather small, to avoid giving the appearance that the foods contain large quantities of undesirable components. different serving sizes within a product class, moreover, make product comparisons difficult.

Although serving size was not a major issue among the many discussed at the FDA/USDA/FTC food labeling hearings or in the written comments, those comments that did address this issue implied that the public would welcome standardization of serving sizes. Three hundred ninety-one commenters said that serving size is an important element of nutrition labeling, and some people noted that the current serving sizes on nutrition labels are misleading.

Because serving size information is important in meaningful nutrition lageling, because of their commitment to make uniform serving sizes for some foods, and because industry has failed to set useful serving sizes in many cases, the agencies have concluded that they should establish serving sizes for foods needing them.

Proposed Actions: FDA will publish final serving size regulations for some beverage products, cereal, and meal replacements. FDA and USDA will propose regulations to establish serving sizes for additional product classes and/or types of foods.

Labeling of Sugars

This issue concerns whether to increase information food labels give about sugars and how to express this information.

No Federal regulations specifically govern the quantitative labeling of a food's content of sugars. Segments of the food industry, notably the cereal industry, voluntarily include a breakdown of carbohydrates in their foods into complex carbohydrates and simple carbohydrates (sugars). They add this information to these foods' nutrition labeling.

Over the past few years, consumers have become increasingly concerned about the quantity of sugars they are consuming. This concern results from a desire to reduce caloric intake, from the acknowledged relationship of sugars to dental caries, and from the possible association of consumption of sugars with other diseases. Some also believe that consumption of sugars is responsible for deteriorating eating habits and a perceived decline in the health of Americans. The only demonstrated hazard that sugars pose to the public health, however, remains their contribution to dental decay.

The results of the food labeling initiative absolutely confirm this increased public interest. (The following discussion groups together all comments on sugars labeling, whether they were made in the context of ingredient labeling or nutrition labeling.) Of all those who commented orally and in writing in response to the agencies' request for comments on food labeling, 27 percent asked for information about sugars—making sugars the food component that generated the most public concern. Eighty-two percent of the 892 people specifying which foods should bear sugar labeling wanted this information on "all" foods. Nine hundred eleven commenters specifically requested that the content of total sugars (61 percent) or added sugars (23 percent) be declared on product labels. More than half of the 1,135 commenters who discussed how to declare the amount of sugars in a food wanted to know the percentage of sugars; 8 percent wanted the amount by weight; 3 percent wanted the amount for both percentage and weight. Approximately 34 percent of the commenters on this question asked generally for the "amount" of sugars in a food without specifying a method for listing. Relatively few commenters (444) expressed a preference for the location of this information about sugars on labels. Over 65 percent of those said they wanted this information on a product's ingredient label, while 28 percent wanted it on the nutrition label.

In the Food Labeling Survey, sugar was the food component of most concern to consumers. It was the most frequently avoided substance (by a reported 24 percent of all consumers), it was the ingredient whose presence in the ingredients list was noticed most often, and it was the substance about which the consumers most frequently wanted information.

Proposed Actions: FDA will propose to amend the nutrition labeling regulations (21 CFR 101.9) to require quantitative declaration of total sugars as part of nutrition labeling. USDA will propose regulations to require, as part of nutrition labeling, quantitative declaration of the total sugars a food contains.

Recognizing that some foods provide insignificant quantities of sugars, the agencies are seeking information on the amount of sugars (grams per serving or percentage by weight) that should trigger the label declaration. FDA, USDA, and FTC have established a task group to develop criteria for determining such a level of sugars. In developing its proposal on this issue, the task group will consider comments it receives in response to this request. The agencies estimate that this assignment will be completed in 4 months after the close of the comment period.

USDA and FDA will seek or support legislation to provide them with explicit discretionary authority to require quantitative labeling of sugars on the basis of public health significance.

To complement their actions on labeling of sugars, the agencies will conduct an educational program to increase consumers' understanding of how sugars are declared on food labels.

This rather involved issue deserves further explanation. FDA has jurisdiction over most sugar-sweetened products, but it does not have explicit authority to require across-the-board quantitative labeling of sugars on all foods. The current authority, among other things, does allow FDA to amend the nutrition labeling regulations to include quantitative declaration of sugars—and the first part of the agencies' proposal shows FDA intends to do so. Public preference on this issue is so clear, however, that a full response to it requires FDA and USDA to seek or to support legislation for discretionary authority to require quantitative labeling of sugars on the basis of public health significance—a second action they propose to take. The agencies have concluded that the declaration of sugars (triggered by a level to be specified) should be based on the total amount rather than the amount of added sugars because (1) a declaration on the basis of added sugars would not provide the complete picture of the total content of sugars in a product, (2) the body cannot differentiate between sugar molecules, whether they are added or not, and (3) analysis to distinguish added from total sugars is difficult, if not impossible, in most instances.

The agencies have further concluded that labeling information on the content of sugars belongs more properly with nutrition labeling because the total sugar content of the product is of foremost importance to the consumer. If the labeling of sugars appeared in the ingredient statement, only added sugars would be declared, even though

indigenous sugars contained in the other ingredients could constitute the bulk of sugars in the product. The agencies have not ruled out the possibility of requiring those foods containing a large amount of sugars to declare this information in the product name, e.g., "Cereal X, contains —— percent sugars."

The form of quantitative declaration (percentage by weight, grams per serving or other units) remains at issue because percentage labeling alone is potentially misleading. A food declaring a higher percentage of sugars than another may in fact provide a lesser amount of sugars per serving than a product with a lower percentage by weight of sugars. Researchers at FDA are now working on this problem.

Sodium and Potassium Labeling

Current FDA (21 CFR 105.69) and USDA (9 CFR 317.2(j)(2) and 381.124, and 7 CFR 2859.411(e)) regulations make the declaration of a food's sodium content voluntary, in the absence of a claim about the sodium content of a food. When a product does bear sodium labeling, its label must list the number of milligrams of sodium per 100 grams and per serving. The regulations do not require sodium declaration as a part of nutrition labeling, and under the present rules, labeling of sodium content does not make full nutrition labeling mandatory.

The sodium content of foods provoked a significant public response. This discussion groups together all of the comments on sodium and potassium labeling whether they were made in the context of ingredient or nutrition labeling. Nearly 25 percent of all commenters discussed this issue in their oral and written statements, making it second only to sugars as the food component whose label declaration most concerned the public.

Public concern about the levels of sodium in the American diet has increased in recent years. This interest arose after several reports concluded that current intake levels exceed physiological needs. The basic question involves the relationship of sodium, derived from salt or other sodium-containing compounds, to hypertension and other physiological disorders. Clinical conditions such as renal disease, requiring control of sodium intake, frequently require the simultaneous control of potassium, and control of potassium often requires sodium control as well. An estimated 20 to 30 million Americans have diseases or disorders for which controlling sodium intake, potassium intake, or both, is important. As a result, many consumers believe that product labels need to display more information about the sodium and potassium content of foods.

Six hundred thirteen commenters specifically addressed whether total or added sodium content should be declared on product labels; 60 percent wanted content declared for total sodium, 23 percent favored listing only added sodium, and 17 percent advocated the declaration of both.

Although 1,063 commenters discussed how to declare the amount of sodium in foods, their suggestions were divided. Forty-nine percent wanted to know the amount of sodium in a product but did not specify what form this information should take. Of those commenters expressing a preference, 24 percent wanted it listed as a percentage and 25 percent wanted it listed by weight. (A few wanted both.)

Finally, as with sugars, not many commenters offered opinions on the placement of quantitative sodium labeling on food labels. Four hundred fifty commenters discussed this question; 60 percent preferred that sodium content appear in the ingredient statement, nearly 35 percent wanted it on the nutrition label, and 5 percent wanted it as a distinct designation on the principal display panel.

The views expressed in FDA's Food Labeling Survey parallel the hearing and written comments. Sodium was second only to sugars as the food component of concern: 13 percent of the respondents reported attempting to avoid consuming sodium whenever possible.

Proposed Actions: FDA will propose to amend its nutrition labeling regulations to require the declaration of sodium and potassium content as part of nutrition labeling.

USDA intends to propose reguations that would require sodium labeling as a part of nutrition labeling, and it will consider including potassium labeling in this proposal.

FDA and USDA will propose regulations to define "low sodium." They will also consider defining "reduced sodium" foods and standardizing the claims appropriate for foods containing no added sodium.

FDA will seek or support legislation to provide it with explicit discretionary authority to require quantitative labeling of sodium and potassium on the basis of public health significance. USDA believes it has such authority but will support legislation to provide more explicit authority for both agencies.

In their deliberations, the agencies considered various options for increasing labeling information on sodium and potassium content. They have concluded that information on sodium and potassium would be better addressed as a part of nutrition labeling because knowing the total sodium and potassium content of the product is most important to consumers. Placement of the sodium and potassium content labeling in the ingredient statement, for example, would require only added sodium and potassium to appear, even if the indigenous sodium and potassium contained in the other ingredients represented the bulk of these elements in the product. In addition, issuing regulations defining "low sodium" and "reduced sodium" foods and standardizing the claims appropriate for foods containing no added sodium should also help consumers monitor their intake of sodium and encourage manufacturers to formulate foods with lower sodium content.

Fatty Acid and Cholesterol Labeling

Fatty acids are present in all fats, and their composition determines whether a fat is "saturated" or "unsaturated." Cholesterol is a fatty substance called a steroid. Consumers are interested in both because of the possible association between their consumption and coronary heart disease. At issue here is (1) whether food labels should present more information about fatty acid and cholesterol content and (2) if so, what such information should include.

FDA regulations (21 CFR 101.25) permit the voluntary inclusion of fatty acid and cholesterol content as part of nutrition information. They allow a food's label to include information on fatty acid content provided the food contains 10 percent or more fat on a dry weight basis and not less than 2 grams of fat in an average serving. If a food product makes any claims about fatty acids and/or cholesterol, the information required by this regulation then becomes mandatory. The label of a food bearing this information must also state the following: "Information on fat (and/or cholesterol, where appropriate) content is provided for individuals who, on the advice of a physician, are modifying their dietary intake of fat (and/or cholesterol, where appropriate)." It is now obvious, however, that many people want to modify their consumption of fat and cholesterol—and are doing so—without specific medical supervision. Such instructions may not, therefore, always be necessary. No specific USDA regulations cover fatty acid or cholesterol labeling, but the labeling of meat, poultry, and egg products follows FDA's guidelines. FTC's Division of Food and Drug Advertising has recommended that the Commission require certain fatty acid and cholesterol

information in advertising making claims in this area.

The public's concern about coronary heart disease, and the belief that this disease may be related to dietary factors—including the consumption of fatty acids and cholesterol—has aroused interest in the amount and kind of fat and cholesterol contained in foods.

Nearly 14 percent (1,346) of all commenters mentioned the labeling of fats and oils in foods. (As in the discussions of sugars and sodium, the comments on fatty acids and cholesterol—whether they were made in the context of ingredient or nutrition labeling—have been combined.) One thousand one hundred and forty-six wanted to know the quantity of fats and oils in food; 1,302 wanted to know the their source; and 458 wanted to know the amounts of unsaturated and saturated fats in foods. Relatively few specified where this information should appear on the food label; of those 321 commenters who specified location, 69 percent wanted this information in the ingredient statement, 28 percent favored locating it on the nutrition label, and 3 percent preferred the principal display panel.

The results of FDA's Consumer Food Labeling Survey confirm this public concern about cholesterol and fat content. Twelve percent of the respondents who claimed they read nutrition labels said that cholesterol is an important item. Given a list of 38 nutrients, 65 percent of the respondents listed cholesterol information as "very important," while 52 percent listed polyunsaturated fats as "very important" and 50 percent said the same for saturated fats. The mandate of consumers is clear, and the agencies agree that increased food labeling information about fatty acids and cholesterol is in order.

Proposed Actions: FDA will continue to require that the cholesterol or fatty acid content of a food be included on nutrition labeling when claims about these substances are made.

FDA will propose to amend the fatty acid/cholesterol regulation to require fatty acid labeling whenever cholesterol is declared and cholesterol labeling whenever fatty acids are declared.

FDA will propose to amend the present fatty acid/cholesterol regulation to eliminate the requirement for the statement "Information on fat (and/or cholesterol as appropriate) content is provided for individuals who, on the advice of a physician, are modifying their dietary intake of fat (and/or cholesterol as appropriate)."

FDA will propose a regulation to define the terms "low cholesterol," "reduced cholesterol," and "cholesterol free." FDA will also consider proposing regulations to govern claims about fatty acid content.

FDA will seek or support legislation to provide it with explicit discretionary authority to require cholesterol/fatty acid content labeling on the basis of significance to public health. USDA believes it has such authority but will support legislation to provide more explicit authority for both agencies.

USDA will propose regulations to require cholesterol labeling as part of nutrition labeling.

Fiber Labeling

Fiber is an essential dietary component for normal bowel function. Some advocates of high fiber diets have theorized that the incidence of bowel cancer and other intestinal diseases may be related to the decreased amount of fiber in Western diets, and these theories have gained a measure of public currency. Some segments of the food industry, especially cereal manufacturers, have increased the use of fiber declaration on product labels in response to the increased public interest. The question here is whether to increase information food labels provide about fiber content.

Until recently, scientists and consumers had only a limited interest in the fiber content of foods. The biomedical aspects of fiber in its various forms are unsettled and the subject still generates considerable controversy. There is no scientific consensus on a definition of "fiber". Both the government and industry are still conducting research to solve the methodological problems related to the several types of dietary fiber. The only official method of analysis currently available is for "crude fiber," which is just a fraction of total dietary fiber. Finally, the relationship of dietary fiber to health remains controversial. FDA regulations (21 CFR 105.3(d)) now require that any disclosure of fiber content must be expressed as "crude fiber" and declared as a percent by weight.

Two hundred seventy-eight commenters (or 8 percent of those commenters specifying what kinds of nutrition information is most important) thought that knowing a food's fiber content is important. Although some consumers have said they want food labels to provide more information about the fiber, many appear to have limited knowledge about fiber content of foods and scant understanding of the differences between crude and dietary fiber. As a result, many may be unable to evaluate information on fiber adequately.

This state of affairs is not surprising, given the scientific uncertainty and controversy involving various aspects of fiber. FDA, USDA, and others currently are conducting research on methodologies for measuring fiber and on the relationship of dietary fiber constituents to health.

Proposed Action: FDA and USDA will not require dietary fiber labeling as part of nutrition labeling until there is a clearer consensus on a definition of dietary fiber, until methods of analysis are developed, and until its significance in the diet is better understood.

Disease-Related Claims on Food Labels

Should FDA and USDA alter their general policy of not allowing medical claims on food labels? FDA regulations (21 CFR 101.9(i)(1)) specifically prohibit claims in labeling that a food is adequate or effective in the prevention, cure, mitigation, or treatment of a disease or a symptom. Similarly, the FTC has challenged such claims in food advertising, and the FTC staff has proposed that the Commission prohibit the use—in advertising—of claims that violate this FDA regulation.

Only 42 commenters expressed views on allowing food labeling or food advertising to make medical claims, and the majority opposed permitting claims such as "this low cholesterol food is beneficial in preventing heart disease" or "this low calorie food will help you lose weight."

Interest in specialized food products available for medical conditions, however, continues to increase. FDA is developing a proposal concerning the labeling of these specialized foods, sometimes called "medical foods." This proposal will cover special foods specifically marketed for use under medical supervision; it will permit those foods—such as products used to treat phenylketonuria—to bear therapeutic labeling.

Some consumers have also shown interest in dietary regimens and special food products for use in preventing colds, causing weight loss, and the like. The current state-of-the-art in nutrition and disease treatment remains insufficiently developed to allow manufacturers of less specialized dietary preparations or conventional foods to make medical claims without being misleading to the consumer. Furthermore, it is the total diet, not an individual food item, that establishes the role of nutrition in determining health and reduces the risk of diet-related diseases.

Proposed Actions: FDA and USDA therefore intend to maintain the present policy of not allowing disease-related claims to appear on the labeling of conventional food products, but they will reexamine this policy if the need arises.

FDA will proceed to develop proposed regulations covering "medical foods" (foods for use under medical supervision), permitting the use of appropriate therapeutic claims about such foods.

Open Date Labeling

The term "open date labeling" refers to readable, understandable dates on food packages that can be used by consumers to tell when a product's quality will change. Traditionally, most dates on food packages have been "closed," which means they are written in code and intended only for the use of manufacturers, distributors, or retailers.

There is widespread consumer interest in open date labeling. Approximately 45 percent of all commenters discussed the issue, putting it third in the hierarchy of public concern, behind ingredient and nutrition labeling. Almost all those who commented on open date labeling favored it for at least some foods. Forty-three percent of those in favor said that all foods should bear open date labels; about 12 percent, however, said that open date labeling should apply only to perishable foods.

In the food labeling notice, the public was also asked what form this date should take. Of the 3,352 commenters addressing this question, some of whom gave multiple answers, 49 percent of the commenters favored expiration dates; 33 percent preferred knowing the date the food was packed; 28 percent supported "pull" dates (the date a product should be removed from the shelf); 16 percent supported freshness/quality assurance dates; and 4 percent recommended that different dates be used for different foods. Of the relatively few (672) commenters who discussed whether open date labeling should be mandatory or voluntary, 94 percent wanted mandatory rules.

Respondents in FDA's Food Labeling Survey also reported widespread interest in open date labeling and a desire to see more foods labeled with such dates. Their responses also parallel the hearing and written comments by expressing a strong preference for an expiration date rather than a pack date or a quality assurance date.

Open date labeling is voluntary under present Federal law. The FD&C Act does not contain any specific provision that requries open date labeling, and FDA currently has no open date labeling regulations. Under the adulteration and misbranding provisions of the act, FDA may require an expiration date when a product would violate the act if it were not sold by a certain date and there is a substantial possibility the violation would occur before sale. This concern is particularly applicable to deterioration that would cause a food to become a health hazard. FDA believes that explicit authority is desirable before it establishes any general requirements in this area.

USDA regulations provide for voluntary open date labeling on meat and poultry products. When an open date is used, USDA requires that it be accompanied by the explanatory phrase, "packed on," "sell by," or "use before" (9 CFR 317.8(b)(32) and 381.129(c)). USDA allows processors to label meat and poultry products with additional statements such as "full freshness 10 days beyond date shown when stored at 40° F or below." USDA egg products regulations require only that the label be marked with the production code or lot number from which the pack date can be determined (7 CFR 2859.411(c)(3)).

Many State and local jurisdictions have taken the lead in requiring open date labeling on certain foods. These requirements, however, often differ from jurisdiction to jurisdiction, and the variation is costly for manufacturers and confusing for consumers. It should be pointed out that the meat, poultry products and egg products inspection acts specifically prohibit State and local governments from imposing labeling requrements on federally inspected products that are in addition to or different from those imposed on federally inspected establishments or plants that operate under the acts. Nevertheless, the agencies recognize the important role that the States and localities have played in requiring open date labeling.

The agencies have agreed that open date labeling is a sound idea, and that the Federal government should act to extend open date labeling to more foods. Further study and discussion is needed to determine which foods should have open date labels and what kinds of open dating ("packed on," "sell by," etc.) should be used. In addition, uniformity in approach is essential. The Federal agencies will work closely with State and local governments to develop a consistent approach that will minimize manufacturers' costs and eliminate consumer confusion.

Proposed Action: FDA will seek or support legislation to provide it with explicit discretionary authority to require open dating on classes of foods as is found necessary. USDA believes it now has such authority but will support legislation to provide more explicit authority for both agencies.

USDA will propose regulations to require open dating on perishable and semiperishable foods to the extent that authority under current law permits.

Imitation/Substitute Foods

This issue concerns the proper labeling of those foods that resemble and are intended to substitute for traditional or standardized products, but do not contain the same ingredients or the same proportion of ingredients. For example, "imitation mayonnaise," resembles the traditional food known simply as "mayonnaise," but the imitation product usually does not contain the same amount of fat, may omit eggs or other ingredients, and may contain ingredients not present in the standardized "mayonnaise."

Under the FD&C Act, an imitation food is considered misbranded if it does not bear the work "imitation" followed by the name of the food it copies. This provision is intended to prevent consumers from being misled into thinking that imitation foods are the same as traditional or standardized products.

Judging from the hearing and written comments, there is considerable public interest in the issue of imitation and substitute foods. Nearly one-fifth of all commenters discussed some aspect of imitation and substitute foods. Of the 1,350 commenters who addressed the issue of naming imitation and substitute foods, the overwhelming majority (75 percent) said that they should be labeld "imitation." Less than one-fifth of the commenters said that such products should be given a new, descriptive name. A few said either approach would be acceptable or that such foods should be given a new name plus the "imitation" label.

Although the comments clearly demonstrate the importance of imitation labeling to the public, they were too general to provide a definitive guide for policy. Imitation labeling is a rather complex issue, and some facets of the issue are very controversial.

Therefore, the agencies are taking no position on the issue at this time, but instead are presenting five possible options to stimulate further public comment. As background to the discussion of these options, both a summary of the main elements of controversy and a description of how the present Federal policy has evolved are in order.

The first element of this problem concerns the meaning of the word

"imitation." Because label space is limited, a single word such as "imitation" is valuable if it can be used in place of several descriptive words. The word "imitation," however, may not mean as much to consumers as its adherents believe, and may even be misleading. The Final Report of the 1969 White House Conference on Food, Nutrition and Health said that the "imitation" label was potentially misleading to consumers; the report noted that this term failed to inform the public about the actual characteristics and properties of a new food, and in some instances unfairly implied inferiority.

Another aspect of the problem concerns innovation. There is nothing in the FD&C Act, the FMI Act, or the PPI Act that explicitly mentions the government's proper role in food innovation. However, the mere presence of governmental regulation, and hence involvement in industry processes, makes the effect on innovation an important issue. Various groups in industry as well as consumers stand to gain or lose depending on governmental policies affecting food innovation. The producers of new and modified products obviously have an interest in governmental policies that make the introduction and marketing of these products as easy as possible, while producers of traditional foods may have their markets reduced by these kinds of policies. Some new and modified foods may have a significant health or price advantage over currently available products, while others may have health and cost disadvantages. Since consumers may stand to gain from one type of new food and lose from another, it is important that they have a basis for perceiving the difference.

A third point concerns the fairness of allowing new products to "co-opt" the names of traditional products. One side argues that new products should be required to establish a market based on their own qualities and intrinsic ability to attract customers, rather than by relying on the goodwill associated with the names of other products whose manufacturer may have spent years developing a market. The other side contends that the consumer is better served by facilitating comparisons among products that are similar and letting the marketplace decide whether the traditional products should have an advantage. Because there are strong arguments on both sides, it is difficult to decide the best government policy. Unfortunately, neutrality is impossible; even a decision to do nothing would be a policy decision that would have consequences in the marketplace.

The Federal policy on substitute foods has evolved over a number of years. As new food products developed, the agencies concluded that some new products were used for the same purposes as traditional foods, but were sufficiently different from their traditional counterparts to make the "imitation" label inappropriate. They also realized that the term "imitation" often connoted inferiority, and that consequently the imposition of "imitation" labeling was probably inhibiting new product development.

A 1973 FDA regulation (21 CFR 101.3) narrowed the use of the term "imitation." Before 1973, "imitation" had to appear on the label of all substitute foods except for a few that went through the process of obtaining a new standard of identity or common or usual name. This policy did not directly take into account nutrient content. Under the 1973 regulation, which is in effect today, however, only nutritionally inferior substitute foods have to be labeled "imitation." Nutritional inferiority is determined by protein content and the content of those 19 vitamins and minerals for which U.S. RDA's have been established. If a substitute food has essentially the same amounts of these nutrients as the traditional food, then it can be labeled with an accurate common or usual name (but still not the traditional name), instead of "imitation." This interpretation of section 403(c) of the FD&C Act has been upheld on judicial review.

It should be noted that the determination of nutritional inferiority under the 1973 regulation does not take into account such factors as carbohydrate, fatty acid, sodium, cholesterol, fiber, and trace element content.

Present Federal policy is based primarily on the 1973 regulation. FDA and USDA make decisions on names for substitute foods that have essentially the same amount of U.S. RDA nutrients on a case-by-case basis. These decisions are usually made in response to a petition for a standard of identity or a common or usual name, or after a manufacturer has gone ahead and given a name to a new food and there is no regulation prescribing a specific name. The FD&C Act does not provide for, and FDA does not require, preclearance of names. USDA, through its prior approval system for labels, does require preclearance. Under certain circumstances, the comon or usual name for a substitute food can include the name of a traditional food and, in some cases, must include the percentage of the characterizing ingredient.

The Federal policy on imitation labeling has attracted considerable interest as the public has become more concerned about the nutritional quality of substitute foods. Of particular interest is the standard for determining nutritional inferiority. Some are concerned that the standard does not take into account the quantities of fiber, all trace minerals, or other micronutrients that may be available in the traditional food. They contend that a person on a diet of substitute foods might develop dietary deficiencies due to the absence or insufficiency of these nutrients. They therefore would prefer use of the "imitation" designation on all substitute foods. In response to these concerns, it should be noted that although these deficiencies are theoretically possible, the data now available do not indicate there currently is a problem.

Some members of the public have also expressed the view that the term "imitation" should be applied to substitute foods that offer no perceived health advantages, but not to foods that do offer such an advantage, e.g., a substitute food containing less fat, sugar, salt, or cholesterol. Still others believe that any change in the proportions of the characterizing or valuable ingredients in a traditional food should render a food an imitation, regardless of its nutrient content. Finally, some people object to including the name of a traditional food as part of the identification of a substitute food, even if preceded by "imitation". They prefer using new names for all new and modified foods.

Just as there are differing views among consumers, industry members also disagree on the issue of substitute foods. Producers of traditional foods naturally tend to believe that totally new names should be used for nontraditional foods. On the other hand, producers of new substitute foods often would prefer to tie their product names as closely as possible to those of traditional foods.

The existing policy does permit manufacturers some flexibility in development and marketing new foods. If the new food meets certain nutritional standards, then it may use a name that affirmatively describes the product. The agencies believe the current policy represents one practical solution to a complex and a controversial issue. They recognize, however, that it has limitations and is not the only possible solution. After reviewing the recent public comments, the agencies also believe that the government has not

adequately explained the policy in the past. Therefore, the agencies want to obtain more comments from the public. They are soliciting comments on the following five options and welcome other suggestions as well:

1. *Maintain the existing policy.* Foods that are not nutritionally inferior to foods for which they substitute do not have to be labeled as imitations but can be given new names that are not misleading. ("Not nutritionally inferior" is defined to mean providing essentially the same amounts of protein and 19 vitamins and minerals for which U.S. RDA's have been established as the foods for which they substitute. It does not include constituents such as fats, fiber, sugars, etc.)

Under this definition, foods that are nutritionally inferior to the foods for which they substitute must be labeled as imitations.

Pro: Manufacturers are encouraged to maintain nutritional quality while affirmatively labeling the product; innovation in food technology is encouraged.

This policy has been upheld by the courts, thus ensuring stability and conserving resources that might have to be devoted to legal challenges if the policy were changed.

It would be the least expensive option because it is already in place.

Con: This policy does not necessarily provide as much information about the substitute food as some consumers may want; it may confuse consumers as to how the substitute food differs from the traditional or standardized food and therefore makes it difficult to shop. It also may be misleading about nutritional value.

It does not differentiate substitute foods that may offer a health advantage from other substitute foods.

It may result in the use of a traditional food's name as part of the common or usual name of the substitute food and, therefore, does not satisfy those who object to use of the name of the traditional food as part of the name of the substitute food.

2. *Expand use of imitation labeling.* (Pre-1973 policy.) Any food that resembles and is intended to replace a traditional or standardized food, regardless of its nutrient content or other characteristics, would be called "imitation" or alternatively, there must be established for this food a common or usual name or a standard of identity. This was the policy before the 1973 regulation.

Pro: It would alert consumers that such foods are not the "real thing" and are intended to replace traditional or standardized foods.

It would avoid the difficult task of determining the adequacy of the criteria used to judge nutritional inferiority.

Con: It would not satisfy those who do not want any use of the traditional name.

The term "imitation" does not tell consumers much about a food because its focus is on what the food is not rather than on what it is. Therefore, consumers will not be adequately informed as to the identity or intended use of the substitute food. It does not differentiate between substitute foods that have a lower nutrient content than the foods they are intended to replace and other substitute foods or between those that may offer a health advantage (e.g., foods that contain less fat or sugar) and those that do not.

The use of the term "imitation", because of its negative connotation, discourages new food innovation and removes the incentive to maintain U.S. RDA nutrient content.

If a common or usual name or standard of identity is sought for such a product, the laborious and expensive administrative process inherent in both approaches could also discourage new food innovation. (Both methods involve notice and comment rulemaking, and the standard of identity approach additionally allows an opportunity for a public hearing.)

3. *Expand use of imitation labeling as described in option 2 but add to the "imitation" designation a common or usual name that explains what the product is.*

Pro: It better informs the consumer about what the product is or is not.

Con: It would not satisfy those who do not want any use of the traditional name (which might be part of the common or usual name.)

It does not differentiate between substitute foods that have a lower nutrient content than the foods they are intended to replace and other substitute foods.

It would call for long labeling (e.g., "imitation cheese and sausage pizza made from 30 percent vegetable oil and soy flour and sausage-flavored isolated protein") that could cause space problems and make labeling less understandable.

4. *Expand use of imitation labeling as described in option 2 but add to the "imitation" designation an explanation (not necessarily as part of the product's name) of how the substitute product differs from the traditional food.*

Pro: It better informs the consumer about what the product is or is not.

Con: It would not satisfy those who do not want any use of the traditional name.

It does not differentiate between substitute foods that have a lower nutrient content than the foods they are intended to replace and other substitute foods.

It could call for even longer labeling than option 3. For example, the name of the product mentioned in option 3 could be "imitation cheese and sausage pizza—this product contains vegetable fat and soy flour instead of milk fat and milk protein normally found in cheese and contains isolated protein rather than sausage." This approach also could label space problems and make labeling less understandable.

5. *Establish a policy based on the proportion and type of characterizing or valuable ingredients.* This option has two components. First, if the proportion of characterizing or valuable ingredients in the food has been changed from that in the traditional or standardized food, the name of the product must consist of the word "imitation" folllowed by the name of the food copied. For example, a substitute for strawberry jam in which the percentage of strawberries has been decreased would be labeled "imitation strawberry jam."

Second, if characterizing or valuable ingredients are replaced, then an accurate common or usual name must be used. This name could include the traditional name only if it described how the substitute food differed from the traditional food. For example, a breakfast meat substitute might be lebeled "bacon-flavored soy protein breakfast strips."

In both cases, fanciful names would also be permitted. For example, the label of the soy protein breakfast product referred to in the preceding paragraph might also include the fanciful name, "Morning Openers." In neither case could the fanciful name include the name of the traditional product, e.g. "strawberry jam" or "bacon."

Pro: Substitute foods would be distinguished from traditional and standardized foods. Substitute foods with different characterizing ingredients would be distinguished from foods with reduced characterizing ingredients. Consumers would receive more information than they now do about substitute foods with different characterizing ingredients.

The policy would partially satisfy those who object to the use of traditional names as part of the name of a substitute food.

It would avoid the difficult task of determining the adequacy of criteria used to judge nutritional inferiority. Criteria based on valuable or characterizing ingredients might be

simpler to administer and communicate to consumers.

Con: Use of the term "imitation" would be retained for some substitute foods. The term "imitation" does not tell consumers much about a food because its focus is on what the food is not rather than what it is.

It would not differentiate between substitute foods on the basis of nutrient content. This would reduce the present incentive to maintain the U.S. RDA nutrient content of substitute foods.

It might not differentiate between those that may offer a health advantage and other substitute foods.

There might be disagreements as to which ingredients in a traditional or standardized food are characterizing or valuable.

It might require a legislative change in the current statute.

Food Fortification

Food fortification involves the enrichment of foods, the restoration of nutrients, and any other addition of essential nutrients to foods; the agencies sought the public's views on whether to increase labeling and quantitative control of fortification.

FDA amd USDA currently have limited control over food fortification, directly through food standards and special dietary food regulations, and indirectly through regulation of imitation and substitute foods and through exercising their authority to prevent misleading labeling. FDA lacks, however, express general authority to control the fortification of foods. USDA under current policy prohibits the addition of vitamins and minerals to meat and poultry products, unless specific regulation permits their addition (as in the case of adding vitamin A to margarine) because no need to fortify these products has been demonstrated. USDA's egg product regulations do allow the addition of vitamins and minerals to products in the way FDA's standards and regulations would allow—unless the purpose of this addition is to make the egg products appear to be better or of greater value than they are (21 U.S.C. 1033(a)(8), 7 CFR Part 2859). Industry has generally added nutrients to foods in a rational way, except in a limited number of special instances involving such products as certain beverages, snack foods, and certain cereals.

Approximately 15 percent of all commenters discussed some aspect of food fortification; 84 percent of the 1,103 commenters who discussed the advisability of fortifying foods gave their unqualified or conditional approval to permitting food fortification.

Of the 340 commenters who gave reasons for fortifying foods, 72 percent favored it to replace nutrients lost in processing, 30 percent to protect the public health, and 14 percent to enhance general nutritional value of the food. (Commenters could list more than one reason.) The most frequent argument against fortifying foods was overfortification, which could cause an imbalance of nutrients in the diet or their excessive intake. Commenters also registered fears that people would replace naturally nutritious foods with fortified foods, that fortification could lessen manufacturers' concern for nutrient retention, or that it could lead to overpromotion of a product. Ninety-four percent of the 401 people who discussed government regulation of forification supported it.

Public reservations thus stem largely from concern about overfortification and the potential for inappropriate fortification; some experts regard deficiency diseases as a concern of the past, and argue that nutrient excesses pose a more substantial problem. Analysis of American dietary practices suggests that this view has some validity, but the subject is complex. Some individuals doubtless consume excessive amounts of some nutrients, such as sodium and phosphorous; but many of these excesses involve personal eating habits and not fortification. And yet a change in the food industry's current restraint toward fortification would be a cause for serious concern, as would an increase in consumption of dietary supplements.

The consumption of fabricated foods intended to substitute for traditional foods does seem likely to increase, and with it the need to ensure that these substitute foods are properly fortified. Furthermore, as Americans reduce their caloric intake, assuring that their diet provides adequate nutrients becomes increasingly important.

Proposed Actions: FDA and USDA will therefore seek or support legislation giving them explicit discretionary authority to control the fortification of food when exercising this control is deemed of public health significance. In the interim, FDA will publish guidelines on food fortification and encourage manufactures to adhere to them.

The agencies agree that any useful food fortification policy must address a number of needs:

1. The need to add nutrients to staple foods to correct deficiencies in a clearly-defined population.

2. The need to avoid adding certain nutrients to foods that are not appropriate vehicles for added nutrients.

3. The need to maintain the total original nutrient profile of foods by restoring nutrients lost in processing.

4. The need to assure that substitute foods are not nutritionally inferior to the foods they replace.

5. The need to require that fabricated foods replacing large portions of the diet or the entire diet have a complete balance of nutrients relative to their calorie content.

6. The need to prevent misleading promotions of fortified foods that present no advantages over other foods.

FDA, USDA, and FTC agree that future food fortification requires appropriate guidance, and they are convinced that such guidance should derive from the legislative authority to control, when public health significance requires it, fortification of foods. The agencies intend to seek this authority, but in the meantime FDA will soon issue a separate **Federal Register** notice entitled "General Principles for the Addition of Nutrients to Foods." Besides providing general guidance on fortifying foods, this notice also explains which foods, such as meat and poultry products and snack foods (carbonated beverages, candies, etc.), FDA considers to be inappropriate for fortification.

Safe and Suitable Ingredients and Food Standards

Understanding this issue requires briefly sketching the history of food standards. Since the early 1940's, FDA has issued regulations called standards of identity which describe what ingredients may or must be used in making many traditional foods. These standards initially were almost strict recipes, although they allowed some minimal flexibility for the use of certain optional ingredients such as colors, flavors, and spices. In other words, they listed the specific mandatory and optional ingredients that the food could contain. These early standards, some of which covered breads, canned fruits, and vegetables, were designed to guarantee the uniform quality and compostion of traditional foods familiar to the American household, to control the use of food and color additives, and to control the basic nutritional quality of standardized foods.

This policy changed significantly in 1961, when FDA issued the breaded shrimp standard (21 CFR 161.175). This standard shifted regulatory focus from all ingredients to the characterizing (mandatory) ingredient(s), which in this case involved the amount and nature of the shrimp. Thus, while this standard specified that such a product must contain 50 percent shrimp, it permitted the use of any "safe and suitable" batter

ingredients. This move toward safe and suitable optional ingredients initiated a period of greater flexibility in FDA's food standards. Standards of identity now allow manufacturers to use any safe and suitable ingredient that performs the function specified in the standard. For example, instead of specifying a preservative by name (calcium propionate, sodium benzoate, etc.), a standard allows any safe and suitable preservative. (Of course a standardized food's label must declare the particular preservative used.) The shift in policy was made possible by enactment of the Food Additives Amendment of 1958 and the Color Additive amendments of 1960 to the FD&C Act, amendments requiring that FDA approve the safety of food and color additives before they could appear in foods. Therefore, FDA no longer had to rely on food standards for premarketing review of the safety of substances added to food. (Before these amendments, only ingredients in standardized foods were subject to premarket approval.)

The phrase "safe and suitable," as defined by regulation (21 CFR 130.3(d)), means that the ingredient it describes:

1. Performs an appropriate function in the food in which it is used;

2. Is used at a level no higher than necessary to achieve its intended purpose in that food; [and]

3. Is either (a) not a "food additive" or "color additive" as defined in section 201(s) or (t) of the FD&C Act as used in that food, or (b) if it is a food additive or a color additive as so defined in those sections, its use conforms with regulations established in accordance with section 409 or 706 of the act.

Thus, the "safe and suitable" policy is applicable only to optional, functional indgredients in standarized foods that are (1) approved food or color additives, or (2) prior sanctioned, or (3) generally recognized as safe—a category known by the acronym "GRAS." These ingredients are generally, but not always, used in small quantities. At the heart of this FDA policy is the principle that manufacturer choice among safe and suitable ingredients in a food with a stardard of identity is not appropriate if the use of the safe and suitable ingredients alters the basic characteristics of the food, whether by degrading its taste, smell, appearance, or nutritional characteristics. The food's label, further, must specifically identify any "safe and suitable" ingredient it contains—except for colors, spices, and flavors, which may be declared generally.

In marked contrast to other food labeling issues, food standards and the related matter of "safe and suitable" ingredients generated a response from only 4 percent of all commenters. They generally sought more information on the ingredients involved. Of 217 comments on the issue of food standards, 41 percent wanted standards eliminated, 23 percent wanted standards applied to more foods, and 9 percent wanted food standards applied to fewer foods. Only 213 comments focused on the flexible uses of safe and suitable ingredients in standardized foods: 62 percent favored making the present "safe and suitable" policy less flexible, 10 percent wanted it more flexible, and 29 percent thought it sufficiently flexible.

The limited amount of public reaction on this issue suggests either that the "safe and suitable" policy concerns consumers relatively little or that their understanding of it is insufficient to permit meaningful comment. Such confusion as exists, the agencies believe, may well be partly due to their failure to explain the concept adequately. They therefore believe it is necessary (1) to explain the policy more accurately and (2) to propose certain modifications to clarify it and to ensure it is applied where appropriate.

Essentially, a standard of identity, according to FDA's current "safe and suitable" policy, only generally identifies certain categories of functional ingredients a food may contain, and it leaves the selection of the specific functional ingredients to the manufacturer. The types of food ingredients in this category would be optional in a standardized food and serve only a functional purpose; the particular functional safe and suitable ingredient a manufacturer chooses must be specifically identified on the food's label (unless, once again, it is a color, spice, or flavor).

One of the major effects of FDA's "safe and suitable" policy, some have alleged , is to shift the burden for establishing the safety of an ingredient from the manufacturer to FDA. Some confusion may result from the name itself, for "safe and suitable" may suggest to some people that FDA exercises only limited control over ingredients in a standardized food. In reality such ingredients generally have undergone the same form of approval, before they reach the market, as ingredients used in nonstandarized foods—prior approval, GRAS, or food and color additive review. The name "safe and suitable" may also imply that FDA's review of a food standard includes an explicit safety review of each ingredient, when in fact questions of ingredients safety are resolved in accordance with other sections of the FD&C Act for ingredients in both standardized and nonstandardized foods. The food and color additive regulations, for example, specify the functions for which these substances may be used and limit the amounts that can be used. Because of the misunderstanding surrounding the name "safe and suitable" the agencies are considering alternative terminology, such as "permitted functional ingredient," which would more accurately describe the policy.

USDA regulations and standards identify acceptable food additives somewhat differently, according to (1) class of substance, (2) specific substance, (3) purpose, (4) product for intended use, and (5) quantity of use. USDA enforces a number of standards of identity or composition and through its label approval system requires minimum amounts of major ingredients in meat and poultry products. For egg products, USDA relies on the standards FDA regulations have established. USDA has, in addition, the authority to preclear labels for meat, poultry, and egg products and to review formulations to determine how food ingredients are used (21 U.S.C. 607, 21 U.S.C. 457, and 21 U.S.C. 1036). FDA does not have authority to preclear food labels (an authority some feel it should have), but assures the safety of food ingredients under other sections of the FD&C Act. Moreover, because FDA is responsible for more foods than USDA, and because of the large number of foods involved, FDA would have insufficient resources to review food labels before a food is marketed, even if it had this authority.

This approach to the approval of "safe and suitable" ingredients saves money—for FDA, for industry, and ultimately for the consumer—without any loss in the integrity of a food. It eliminates the need for lengthy and expensive administrative proceedings to amend a food standard each time a manufacturer wants to use a new or different ingredient in a standardized food. Amending a standard, for example, under the normal administrative procedures of the FD&C Act takes at least a year (and costs a minimum of $40,000); a more complex amendment may take 6 or 7 years. FDA completes the processing of about seven amendments annually. The costs to industry for petitioning to change a single standard also are high. The true cost of the amendment process becomes evident when one recognizes that FDA has issued about 275 stardards of

identity, each encompassing at least one food.

Allowing the use of optional functional ingredients permits a manufacturer of food processor to use different ingredients in response to seasonal changes, economic conditions, or the availibility of a new ingredient. The manufacturer must, of course, change the ingredient statement on the food label accordingly. The important point to remember is that this flexibility can translate into savings for consumers without reducting the quality of a food; furthermore, this policy is fairer because it allows the same flexiblity for certain functional ingredients in standardized foods that the FD&C Act permits for all ingredients in nonstandarized foods.

The agencies will *propose* the following modifications in the current policy, but before doing so, they would like to have the public's comments on the revised policy. The new policy would:

(1) Apply only to optional, functional ingredients used in quantities of less than 5 percent. For the purpose of this policy, the term "functional ingredients" would be defined as ingredients that do not alter the basic characteristics of the food.

(2) Require the declaration, on the product's label, of any ingredient that product contains (as now required for nonstandarized foods regulated by FDA and all USDA regulated foods except for colors, flavors, and spices.)

(3) Change the descriptive phrase "safe and suitable" to one, such as "permitted functional ingredient," that is less confusing and that more accurately describes this concept.

Miscellaneous Food Labeling Issues

Label Declaration of Country of Origin for Imported Foods

A small number of commenters (117) discussed whether the country of origin should be declared in the labels of imported foods. Most of them were concerned that the label on meat products does not have to list the country of origin if this product was made from imported meat combined with domestic meat, e.g., Argentine beef combined with American beef in ground beef.

Under the Tariff Act, administered by the U.S. Bureau of Customs, Department of the Treasury, an imported product entering the United States must bear the English name of the country of origin to inform the "ultimate purchasers" where the product was made. Generally, "ultimate purchaser" is defined as the last person in the country who will receive an article in the form in which it was imported. If the product is repackaged or porcessed further in the United States, the repackager or processor becomes the "ultimate purchaser," and the repackaged or converted product need not declare the country of origin. However, if the food is sold at retail in its imported form, then the product must bear the name of its country of origin.

The laws administered by USDA and FDA require that imported products meet the same standards as American-made products. FDA laws do not contain any provisions pertinent to country of origin labeling. USDA laws and regulations are consistent with the Tariff Act provision on country of origin labeling.

Problem would arise if the country of origin labeling requirement were extended to imported foods that are repackaged or further processed in the United States. Food producers generally purchase ingredients from several foreign sources and use them in a variety of products. For example, cacao beans are purchased from several countries in South America and Africa and are used in making cocoa and chocolate, which are in turn used in making a multitude of products. A country of origin requirement in such cases could be expensive, both in terms of industry's ability to comply and the agencies' ability to monitor. Furthermore, it could cause label space problems. The agencies do not believe that the costs to industry, which ultimately would be passed along to consumers, as well as the enforcement costs for the Federal government would result in any substantial consumer benefits.

Proposed Action: USDA and FDA will continue the present policy requiring that the country of origin be declared on the label for foods imported in packages and sold in such packages at retail. The policy will be reexamined in the future if necessary.

Label Declaration of Name and Address of Manufacturer, Packer, or Distributor

The current laws administered by FDA and USDA require that food labels bear the name of the manufacturer, packer, or distributor. In addition, USDA requires meat, poultry, and egg products to bear an inspection legend and a number identifying the establishment or plant that prepared the product. A few commenters (40) said they wanted labels to list the food's manufacturer or packer in those cases where the label bears only the distributor's name. Their reason for wanting this information was based primarily on their right to know, although a few wanted it so they could write directly to a manufacturer for further information.

The required listing of manufacturer or packer would have a major impact on firms such as chain supermarkets that buy a product from a manufacturer and then sell it under their own label. Many of these stores purchase from different sources at different times depending upon competitive bids. They would incur the additional costs of maintaining a large label stock, revising labels, and segregating products during labeling. The agencies have concluded that the potential costs of such a requirement to food labelers would outweigh the projected benefits to consumers.

Proposed Action: USDA and FDA will continue the present policy of requiring declaration of the name and address of the manufacturer, packer, or distributor. The policy will be reexamined in the future as found necessary.

Natural and Organic Labeling Claims

At the present time, FDA and USDA take differing approaches to the use of "natural" and "organic" claims on food labels. FDA does not attempt to restrict such claims because it believes that the development and enforcement of standards in this area would be difficult and might unjustifably imply to consumers that food labeled "organic" or "natural" are inherently superior to other foods in nutrient content and safety. USDA, on the other hand, does attempt to control the use of "natural" and "organic" claims on meat, poultry and egg products because it believes such claims are generally misleading. USDA enforces this approach through its prior lable review program.

In late 1974, FTC proposed a trade regulation rule to eliminate the possibly unfair and deceptive use of a number of different types of claims in food advertising, including claims that foods are "natural" or "organic." In proposing this rule, the Commission stated its concern about the ability of consumers to understand natural and organic claims which are used in a wide variety of confusing and conflicting contexts. The Commission called for public comment on ways to improve this situation, including comment of a staff proposal to prohibit the use of the terms "natural" and "organic" and on the possibility of setting standards to prevent the unfair and deceptive use of natural and organic advertising claims.

In late 1978, after extensive written comments and testimony by scientists, consumer and industry representatives, and others, the staff of the Division of Food and Drug Advertising recommended that the Commission promulgate a final rule. This rule would,

among other things, establish standards to prevent the unfair or deceptive use of natural and organic food claims (i.e., foods not meeting these standards could not be advertised as natural or organic) and prohibit claims that foods advertised as "natural" or "organic" are inherently superior to other foods in their nutrient content or safety.

The recommendations of the Division of Food and Drug Advertising are based on evidence that current uses of "natural" and "organic" claims are confusing and misleading to consumers and frequently violate the public's legitimate expectations about their meanings. The staff also concluded that these claims could provide useful information if unsupportable superiority claims were prohibited and if the claims met standards embodying the major elements of each concept. The basic elements in these standards are as follows:

A food may not be represented as natural or a natural food if (a) it has undergone more than minimal processing or (b) it contains any artificial or synthetic ingredient.

A food may not be represented as organic, an organic food, or as having been organically grown if (a) the soil in which it was grown was subjected to fertilizers other than organic materials or certain minerals or (b) any artificial or synthetic chemical (e.g., a pesticide or herbicide) has been directly applied in its production.

The Director of Bureau of Consumer Protection and the Commissioners have not yet decided whether or not to accept these recommendations. Final Commission deliberations are expected to take place in the near future.

Proposed action: USDA and FDA will continue their current policies for regulating "natural" and "organic" claims pending their evaluation of FTC's rulemaking efforts. They will then determine whether additional action on such labeling claims is necessary.

USDA and FDA agree with the FTC staff that because it is false and misleading to claim that foods described as natural or organic are inherently superior in nutrient content or safety, such claims should be prohibited.

Quantity of Contents Declaration

Approximately 12 percent of all the commenters addressed issues related to the declaration of quantity of contents on food labels. At least 71 percent of those focusing on how this declaration should be made favored some form of solid or liquid weight labeling. About half expressly requested the use of drained or solid weight content, particularly for canned fruits and vegetables. Almost 27 percent of the commenters wanted a product's net weight to appear on the label, either alone or in conjunction with the package's drained or fill weight. Approximately 11 percent wanted to know the amount of liquid in a product, while 6 percent wanted a product's fill weight declared on the label.

In FDA's Food Labeling Survey, 60 percent of the users of canned food products did indicate a desire for drained or fill weight labeling when asked directly if they would like to have this information. Only 3 percent mentioned wanting this information when asked what additional information they would like to have on canned food labels.

On November 7, 1975 (40 FR 52172), in response to a petition from Consumers Union, FDA published a proposal to require label declaration of the drained weight of canned fruit and vegetables. (Drained weight is the weight of the food in a can after thermal processing and does not include the weight of the packing medium.) FDA received more than 6,000 comments on this proposal, mostly from consumers who favored drained weight label declaration.

The National Food Processors Association later petitioned for an alternative to drained weight: declaration of fill weight. (Fill weight is the weight of the food in a can, exclusive of the packing medium, when placed in the can.) A study by one industry organization and a similar study conducted under contract for FDA showed that drained weight labeling would cost about 10 times more than fill weight labeling. The cost difference between drained weight and fill weight labeling is approximately $100 million versus $10 million.

On December 9, 1977 (42 FR 62282), FDA proposed that manufacturers be allowed to use fill weight or drained weight labeling under certain prescribed conditions. The comment period on FDA's proposal ended July 1, 1979. This lengthy comment period gave the canning industry two packing seasons to test its ability to comply with the proposed requirements, and gave consumers an opportunity to become familiar with the type of labeling proposed and to comment on its usefulness. FDA is now evaluating the comments, and will publish a final regulation shortly.

The USDA follows a policy that requires the net weight of canned products to reflect the solid weight only, unless the packing medium has nutritive value.

The Total Food Label

Labels have a limited amount of space on which to put a large quantity of information. Some of this information is required by law: common or usual name of the food; name and address of packer, manufacturer, or distributor; listing of ingredients for most foods; presence of artificial flavoring, coloring, or chemical preservative; and the amount of food contained in the package. Nutrition labeling is required by regulation if vitamins, minerals, or protein are added to the food or if nutrition claims are made. The nutrition label may contain up to 28 pieces of information, including the amount of vitamins, minerals, calories, protein, carbohydrate, and fat present in the food. In addition, the label may contain other information that the manufacturer wishes to put on it, such as a brand name, the price, vignettes or product photographs, serving directions, recipe suggestions, offers to send information, premium offers, product guarantees, product coupons, advertising/benefit claims, ethnic symbols, the universal product code, dating, patent numbers, and/or storage directions.

Comments

Although there were not a large number of comments on the total food label, the agencies have drawn some general impressions from the public's responses. Commenters emphasized the need to make food labels more intelligible to the average consumer. They generally recommended that labels be written clearly and concisely and that they use simplified, standardized, nontechnical language.

A number of commenters offered suggestions for improving the format of food labels: 352 commenters specifically stated that the type size on labels should be increased. In support of this request, commenters pointed out that much of the small print on labels is illegible, so individuals with sight problems, particularly the elderly, cannot read it. Commenters also said that better contrasting colors should be used to make information more readily distinguishable, that information should be placed in a uniform location on all labels, and that overcrowding or cluttering information should be eliminated. Some suggested that some information now appearing on labels could be eliminated to make room for more necessary information and to prevent "information overload" on food labels. They suggested that special recipes, cooking instructions, advertising or promotional information, special gift or coupon offers, and fanciful labeling in

general be eliminated. In fact, several commenters specifically expressed their support for the "no frills" labels or the "plain package" product, as long as the quality of the product remained unchanged.

In contrast, other commenters remarked that they would like to have much of the descriptive information remain on or be added to food labels. The items requested were product identification, cooking instructions, unit price, recipes, pictures, and religious identification.

A number of consumers also said they wanted symbols to indicate the presence of certain ingredients, e.g., foods high in sugar, foods high in salt/sodium, or foods containing artificial colors or flavors. The agencies will explore further the practicality and desirability of using symbols for various purposes.

Some commenters advised the agencies to proceed cautiously before substantively overhauling existing regulations. They pointed out that the food label could not reasonably be expected to provide all the information requested by consumers and that any changes should be implemented only after the agencies have carefully evaluated the potential benefits relative to possibly increased costs. Some stressed the need for stability in food labeling, emphasizing that consumers would learn to utilize the information only if there are relatively few changes so they can become familiar with them. Moreover, some commenters emphasized that label changes should fulfill clearly defined objectives and supported development of a total food labeling strategy rather than implementing a piecemeal series of changes.

Label Format Research

The public hearings, written comments, and consumer research have focused on "what" information should be communicated to consumers. The next question is "how" to communicate this information. To answer that question, FDA will conduct a research program, supported by USDA, to help decide what labeling format is the most comprehensible to consumers. This program will employ professional communications experts in the private sector to design alternative labeling formats that will be subjected to consumer testing. Designing alternative labeling formats has begun, and the actual consumer testing will begin this fall and extend into 1980. Nutrition labeling and ingredient labeling will be the primary focal point for this research.

Nutrition labeling research will center on developing a number of graphic or pictorial formats, including bar charts, pie charts, etc., that can be compared with the current systems. Ingredient labeling research will include the design and testing of formats for declaring ingredients by percentage and weight, as well as various organizational schemes aimed at communicating more intelligibly what the food ingredients are, e.g., listing names of the characterizing ingredients.

After the formats for the nutrition and ingredient labels are designed, alternative formats for the total food label will be designed. These will include all the information required by law, plus that information that currently is discretionary (e.g., vignettes, cooking directions, premium offers, etc.) in an effort to determine the best overall format.

Other areas of food labeling research probably will include possibilities for "flagging" ingredient changes on food labels and the use of symbols and summary statements to assist in identifying foods containing high or low quantities of sugars, sodium, cholesterol, or calories.

The various formats decribed above will be tested on different types of consumers, including those with limited education, the elderly, and the poor. This is an opportunity for industry to demonstrate its cooperation in improving food labels. The agencies invite industry to participate in the development of an improved nutrition labeling format. They also encourage and will consider their well-conceived studies by industry on other parts of the food label, such as quantitative ingredient labeling, type size, better contrasting colors, and labels that are simpler and easier to read. Like the agencies' suggestion for nutrition labeling format, a joint cooperative study program would be most effective and efficient and in the consumer's best interest.

Digest

Below are tables that summarize how the agencies propose to proceed in addressing the food labeling issues.

Issue	Legislation	New or revised regulations	Consumer education/ industry guidance	Action deferred pending research, study or future reexamination
I. Ingredient Labeling				
A. Labeling of Mandatory Ingredients in Standardized Foods.	FDA proposes to seek or support legislation to amend the FD&C Act to require declaration of mandatory ingredients in standardized foods. (The regulations issued under statutes administered by USDA already so provide.).	FDA intends to expedite amendment of the remaining food standards of identity to require declaration of all optional ingredients including the form of the mandatory ingredients where more than one form is available for use.		
B. Label Declaration of Colors, Spices, and Flavors.	FDA proposes to seek or support legislation to require that all colors and spices be declared on food labels by their specific name.			
	USDA believes it has authority to require the declaration of spices and colors by their specific name but will support legislation to provide more explicit authority for both agencies.			
	FDA proposes to seek or support legislation to eliminate the exemption under which the labels of butter, cheese, and ice cream are not required to declare the presence of an artificial color.			
	FDA proposes to seek or support legislation to provide it with discretionary authority to require label declaration of a flavor when it is considered necessary for providing important health information, e.g., it has a potential for causing an allergic reaction.			

Issue	Legislation	New or revised regulations	Consumer education/ industry guidance	Action deferred pending research, study or future reexamination
	USDA believes it has authority to require declaration of flavors, but will support legislation to provide more explicit authority for both agencies.			
C. Quantitative Ingredient Labeling.	FDA proposes to seek or support legislation explicitly giving it authority to require quantitative ingredient labeling as part of the ingredient statement and to seek or support legislation giving FDA records and reports authority—access to a company's formulae, quality control records and related records in order to ensure that such expanded quantitative ingredient labeling is truthful and accurate.	FDA intends to expand the use of percentage of valuable and characterizing ingredients according to its regulations on common or usual names for nonstandardized foods. USDA intends to issue regulations that would provide for more quantitative ingredient labeling.	FDA intends to publish guidelines for voluntary quantitative ingredient labeling as part of the ingredient statement.	
	USDA currently has limited authority to require quantitative ingredient labeling in some cases, and it shares FDA's belief that legislation establishing the authority of the two agencies generally to require such labeling is desirable.			
D. Ingredient Order of Predominance Statement.		FDA and USDA intend to amend the regulations to require that food labels bear a statement to the effect that the ingredients are listed in descending order of predominance.		
E. Use of "and/or" Labeling to Declare the Source of Fats and Oils.		FDA and USDA intend to amend the regulations to require that food containing 10 percent or more total fat on a dry weight basis declare the specific source of the fat or oil. Food containing less than 10 percent fat on a dry weight basis may use the "and/or" approach, e.g., vegetable oil (may contain cottonseed oil, soybean oil, and/or palm oil)".		
F. Functionality and Names of Ingredients.				The agencies intend to explore the concept of an "ingredient dictionary," a reference volume that would describe ingredient functions, and how such a publication should be compiled, distributed and funded.
G. Labeling of Fresh Fruits and Vegetables.			FDA will continue to encourage compliance with the Federal law which requires that the presence of colors, preservatives, and waxing be declared in labeling (e.g., placards and leaflets) at the point of sale of fresh fruits and vegetables.	The labeling of fresh fruits and vegetables as to pesticides and fertilizers will be reexamined in the future as necessary.
H. Ingredient Labeling for Restaurant-Served Foods.				The agencies will not initiate any action at this time to require that ingredients in restaurant-served foods be declared. This issue will be reexamined in the future as necessary.
I. Incidental/Secondary Ingredients				The current policy of not requiring the declaration of incidental/secondary ingredients will be continued. This issue will be reexamined in the future as necessary.
II. Nutrition Labeling				
A. Mandatory, Discretionary, or Voluntary Nutrition Labeling.	FDA and USDA propose to seek or support legislation to clarify their authority to require nutrition labeling on all foods. (The agencies are establishing a task group to develop criteria for determining which foods should bear nutrition labeling).	USDA intends to propose regulations that would require nutrition labeling where claims are made for a product or where certain nutrients have been added to the product.		
B. Nutrition Labeling Format			The agencies encourage industry to experiment voluntarily, under controlled conditions and in collaboration with FDA and USDA, with graphics and other formats that are consistent with the current quantitative system.	FDA will conduct research, with support from USDA, to determine which format is most useful and convenient for consumers: the present nutrition labeling system will be retained pending research results and conclusions about what (if any) changes in labeling format are appropriate. (An interagency task group will be established to coordinate the research efforts with industry experimentation.)
C. Mandatory Information for Nutrition Labeling.		USDA intends to propose regulations that would require nutrition labeling providing information on calories, protein, carbohydrates, fat, sugars, cholesterol, sodium, and other nutrients of public health concern insofar as permitted by current authority.		FDA and USDA will maintain their current policies on declaring nutrients. Comments are requested on aspects of the present policies.

Issue	Legislation	New or revised regulations	Consumer education/ industry guidance	Action deferred pending research, study or future reexamination
D. Composite Data Base for Use in Nutrition Labeling.			FDA and USDA are issuing a statement of current policy concerning use of suitable nutrient data bases in nutrition labeling.	The agencies propose to maintain the current policy that products be labeled according to composition and that it is the manufacturer's responsibility to assure the validity of nutrient content expressed on food labels. The agencies encourage industry to develop suitable data bases for use in nutrition labeling.
E. Serving Sizes		FDA intends to publish final regulations for some beverage products, cereals, and meal replacements.		
		FDA and USDA intend to propose regulations to establish serving sizes for additional product classes and/or types of foods.		
F. Sugars Labeling	FDA and USDA propose to seek or support legislation to provide them with explicit, discretionary authority to require quantitative labeling of sugars on the basis of public health significance.	FDA intends to amend the nutrition labeling regulations to require quantitative declaration of total sugars as part of nutrition labeling when contained above a specified level.	The agencies propose conducting an educational program to promote better understanding of declaration of sugars.	
		USDA intends to propose regulations to require the declaration of sugars content as part of nutrition labeling. (The agencies have established a task group to develop criteria for determining the threshold level for this declaration).		
G. Sodium and Potassium Labeling.	FDA proposes to seek or support legislation to provide it with explicit discretionary authority to require quantitative labeling of sodium and potassium on the basis of public health significance.	FDA intends to amend the nutrition labeling regulations to require sodium and potassium labeling.		
	USDA believes it has such authority, but will support legislation to provide more explicit authority for both agencies.	USDA intends to propose regulations to require sodium labeling as part of nutrition labeling. USDA will consider the inclusion of potassium labeling.		
		FDA and USDA intend to propose regulations to define "low sodium." Consideration will be given to defining "reduced sodium" foods and standardizing the claims appropriate for food containing no added sodium.		
H. Fatty Acid and Cholesterol Labeling.	FDA proposes to seek or support legislation to provide it with explicit discretionary authority to require cholesterol and fatty acid labeling on the basis of significance to public health.	FDA will continue to require cholesterol or fatty acid content to be included on nutrition labeling when cholesterol or fatty acid claims are made.		
	USDA believes it has such authority but will support legislation to provide more explicit authority for both agencies.	FDA intends to amend the fatty acid/cholesterol regulation to require fatty acid labeling whenever cholesterol is declared and vice versa.		
		FDA intends to amend the fatty acid/cholesterol regulation to eliminate the physician advice statement.		
		FDA intends to propose regulations to define the terms "low cholesterol," "reduced cholesterol," and "cholesterol free." FDA will consider proposing regulations to govern claims about fatty acid content.		
		USDA intends to propose regulations to require cholesterol labeling as part of nutrition labeling.		
I. Fiber Labeling				FDA and USDA will not require dietary fiber labeling as part of nutrition labeling until dietary fiber can be better defined, methods of analyses can be developed, and its significance in the diet determined.
J. Disease-Related Claims on Food Labels.		FDA intends to propose regulations covering "medical foods," that is, foods which are intended for use under medical supervision; the regulations will permit the use of appropriate medical claims about such foods.		FDA and USDA will maintain the present policy of not allowing disease-related claims to appear on the labeling of conventional food products. This policy will be reexamined in the future if found necessary.

Issue	Legislation	New or revised regulations	Consumer education/ industry guidance	Action deferred pending research, study or future reexamination
III. Open Date Labeling	FDA proposes to seek or support legislation to provide it with explicit discretionary authority to require open dating on classes of foods as is found necessary.	USDA intends to propose regulations that would require open dating on perishable and semi-perishable foods to the extent that authority permits.		
	USDA believes it now has such authority, but will support legislation to provide more explicit authority for both agencies.			
IV. Imitation/Substitute Food Labeling.				The agencies have not taken a tentative position pending consideration of further comments on the policy direction they should follow.
V. Food Fortification	FDA and USDA propose to seek or support legislation aimed at providing explicit discretionary authority to control fortification of food when deemed of public health significance.		FDA will publish "General Principles for the Addition of Nutrients to Foods," and encourage manufacturers to adhere to these guidelines.	
VI. Safe and Suitable Ingredients and Food Standards.		FDA intends to revise its "safe and suitable" ingredients policy as follows in order to clarify the policy and ensure that it is only applied where appropriate: this policy is applicable only to optional, functional ingredients used in quantities of less than 5 percent; the descriptive phrase "safe and suitable" will be changed to one that is less confusing and more accurately describes the concept, e.g., "permitted functional ingredient".		
VII. Miscellaneous				
A. Label Declaration of Country of Origin for Imported Foods.				USDA and FDA propose to continue the present policy that the country of origin be declared on the label only for those foods imported and sold in consumer packages as such. This policy will be reexamined in the future as necessary.
B. Label Declaration of Name and Address of Manufacturer, Packer, and/or Distributor.				USDA and FDA propose to continue the present policy of requiring the declaration of the name and address of the manufacturer, packer, or distributor. This policy will be reexamined in the future as found necessary.
C. Natural and Organic Labeling Claims.				USDA and FDA propose to continue their respective policies for regulating "natural" and "organic," claims pending their evaluation of FTC's rulemaking efforts on advertising making such claims.
D. Quantity of Contents Declaration.		FDA will publish a final regulation.		

Request for Economic Information

Before taking specific action to change the current legal requirements for food labeling, the agencies want to allow further public comment on these tentative proposals. Although in some instances making these changes may require additional explicit legislation, FDA and USDA will act promptly, after fully reviewing the comments, to do what they can under their current legal authority and mandate to implement their proposals.

Detailed analysis of the economic impact of these initiatives is warranted before the agencies select specific proposals and courses of action. The agencies are therefore asking the public for information, data, or analyses to help them predict and quantify the economic impact of their proposals on industry and consumers. This information may relate to product categories, package types, characteristics of firms or establishments, manufacturing and distribution practices, etc. The agencies are particularly interested in the cost implications of the following initiatives:

Ingredient Labeling

1. Expanded label identification of ingredients in standardized foods.

2. Expanded quantitative label identification of valuable and characterizing ingredients of foods.

3. Restricted use of "and/or" labeling for fats and oils.

4. Compilation and distribution of a standard ingredient handbook or dictionary explaining the functions of ingredients used in food products.

Nutrition Labeling

1. Mandatory inclusion of sodium and potassium content as part of nutrition labeling.

2. Mandatory inclusion of sugars content as part of nutrition labeling.

3. Mandatory fatty acid labeling when cholesterol content is declared, and mandatory cholesterol declaration when fatty acid content is declared.

4. Other revisions in the mandatory list of nutrients.

5. Mandatory nutrition labeling, regardless of a food's specific content.

6. Optional use of composite data bases for nutrition labeling.

A number of the preceding initiatives may have common economic impacts. But some are alternative impacts, and in those cases the agencies will be interested in trade-off analyses. Specifically, they would like to know whether various actions might lead to:

a. More frequent label changes (possibly requiring multiple label inventories and switching, one-time or continuing cost increments for printing plates, or other costly responses);

b. Reduced flexibility in selection or substitution of ingredients;

c. Increased control of ingredient quantity and/or quality;

d. Increased control of nutrient quantity or stability; or

e. Increased testing for nutrient content.

Data on these (and any other) cost impacts will be most meaningful if they assess individual initiatives. In at least two areas, however, more general data will be useful if they are reliable and detailed:

1. Direct costs of a label change and how these may vary with type of packaging, extent of redesign, number of different sizes or types of package per product, in-house versus outside labeling, lead time available, and so on. Information on this point should specify the steps entailed in changing the label, and the cost of each.

2. Costs of testing for nutrient content and how these may vary with the number and identity of the nutrients to be tested, sample size and number of samples, nature of the product, frequency or regularity of testing, degree of precision or reliability required, and the like.

To aid the presentation of information and data about, an analyses of, each initiative's economic impact, the agencies have outlined their preliminary views on potential issues and questions of cost impact—and the public is invited to comment on these views as well:

1. *Identification of mandatory ingredients in standardized foods*—This initiative requires legislation to amend the FD&C Act to require that mandatory ingredients in standarized foods be declared on product labels. It also simply affirms FDA's intention to complete the continuing effort to amend food standards to require the identification of as many ingredients as possible (1) by making specific forms and varieties of mandatory ingredients "optional" (only "optional" ingredients in standardized foods must be declared) and (2) by requiring that all optional ingredients be declared. This effort will make certain standardized foods conform with the great majority of foods, whose labels already identify all ingredients. This initiative affects a limited number of products because it involves only standardized foods, because some standards have already been amended, and because some manufacturers now voluntarily declare mandatory ingredients. Moreover, because manufacturers already have the requisite information from their own recipes, the cost impact appears to be limited to a one-time label change.

2. *Quantitative ingredient labeling*—Expanded quantitative listing of valuable and characterizing ingredients would require food labels to declare percentage amounts of ingredients that have a material bearing on consumers' acceptance of the product or on its price. Actual quantities may exceed declared values. Although the direct cost will be that of a label change based on the receipe, other costs may be incurred, such as those involving (1) stricter adherence to good manufacturing practices (to maintain a product's uniformity) and (2) keeping the proportions of ingredients more constant.

3. *Restricted use of "and/or" labeling for fats and oils*—Limitation of "and/or" labeling to products in which fats constitute less than 10 percent of the dry weight appears to affect relatively few product categories in the jurisdiction of FDA and USDA; the most obvious are cookies and crackers, blended flour preparations such as cake mixes, canned seafoods, and soups. The agencies are seeking information that will identify the full range of products affected by a 10 percent cutoff level, a 5 percent level, and a 2 percent level—along with the nature of any cost impacts these levels produce. The agencies also are asking for any cost impact information on the effect of combining a labeling requirement for foods with 2 grams of fat per serving with any of these percentage cutoff levels. FDA and USDA will consider these economic data in conjunction with comments received on the nutritional and health considerations as they evaluate the possibility of setting an appropriate cutoff level.

The agencies are assuming that the economic advantage of "and/or" labeling is that it enables firms to switch fats and oils, or their proportions in the product, in response to their price or availability, without necessitating label changes. It would be instructive to have information on how frequently food producers actually make such substitutions and how frequently label changes would be required in the absence of the "and/or" option.

The agencies also need evidence about the kind and degree of cost impact that could result from industry's response to eliminating the "and/or" option. More frequent label changes and the maintenance of multiple label inventories would represent an incremental cost; reduce flexibility of substitution among fats and oils, possibly expressed in higher average costs, more variable and unpredictable costs for total fats and oils used; increased lot purchase sizes and storage costs; or in a combination of these.

4. *Functionality of ingredients*—An ingredient "dictionary" appears to be an efficient means of explaining to interested consumers the function of ingredients used in food products. This could be a voluntary enterprise of the food industry or a project of the government, using—as necessary—data supplied by industry. The resulting publication could be widely distributed (available at no or little cost at most food stores, for example) or somewhat less readily available by offering it for sale, or even free, as a government or private document. (Free distribution to all public libraries is also an option here.) The feasibility of such a project would seem to depend on industry's willingness to cooperate, the number of substances requiring coverage, the frequency of revision and updating, and the expense. The expense would in turn depend on the costs of compiling the data, printing the dictionary, and distributing it—and they would vary with the size of the publication and the scale of its distribution. Because compiling an ingredient dictionary provides an alternative to listing on food labels the functions of ingredients, appraisal of the comparative merits and costs of the two approaches particularly interests the agencies.

5. *Increasing information on sodium, potassium, sugars, fatty acids, and cholesterol content*—The agencies are proposing to require mandatory declaration of sodium and potassium content, and the amount of sugars a food contains, as part of nutrition labeling. In addition, FDA will amend its regulations to require fatty acid labeling whenever cholesterol is declared, and to require labeling of cholesterol content when the food label declares fatty acids. USDA intends to propose nutrition labeling that would include information on the sodium, sugars, and cholesterol foods contain. Because this labeling will require declaring the total content of these substances, the initial establishment of reliable values would probably entail incremental costs. In products to which the manufacturer adds all or most of the substances directly, such testing costs might be nil

or virtually so. In products with food ingredients containing significant and variable amounts of these substances, more frequent testing could be necessary to obtain accurate information. The agencies therefore request evidence on the identities of food products that will require frequent testing; they are particularly interested in products that are believed to present unusual testing requirements because of wide natural variation in the substances these foods contain.

The agencies are seeking comments on the allowable range of variation in a food label's declaration of these substances. Selecting a reasonable tolerance level can reduce costs of testing to ensure compliance; frequency of reformulation could also affect cost, because it might require multiple testing and different labels. Therefore, manufacturers could be faced with a trade-off between the cost of reformulating foods (and keeping multiple label inventories) and the cost of reduced flexibility in altering ingredients that change the nutrient composition of the food.

The agencies also need (a) data on the incremental unit costs of preparing and testing samples for each of these additional substances, both individually and as part of a comprehensive nutrient assay, and (b) estimates of absolute and percentage increases in total testing expenses, for various products, that might be generated by adding these substances to the list of nutrients. They welcome information about any related costs, such as increased requirements for quality control or stabilization of content.

6. *Other revisions in mandatory list of nutrients*—As they assess possibilities for a specific proposal to revise the mandatory list of nutrients, the agencies wish to consider cost implications, as well as the utility to consumers, of alternative requirements. They request three kinds of cost data. First, assuming that any additions to the list would most likely be certain micronutrients such as folic acid, cooper, and zinc, evidence is needed on the extent of additional testing that might be required in various products or product groups, the incremental costs of such testing, or any unusual problems that might arise. A second possibility is reducing the mandatory list to serving size, servings per container, calories, protein, fat, carbohydrates, sugars, sodium, potassium and cholesterol/fatty acids. Added vitamins or minerals, or those about which claims are made, would also require a statement of content, but declaring all others would be optional. The agencies seek comments and estimates on how, and to what extent, such a change might reduce costs and on any problems that might arise from reducing the uniformity of information. A third possibility might exempt mandatory nutrients present at less than 2 percent of the U.S. RDA per serving from disclosure on the label. The agencies also want information on the nature and size of any cost savings this exemption offers.

7. *Composite data bases*—Giving formal recognition to adequately supported data bases providing the nutrient content of various foods may reduce the cost, and thereby increase the attractiveness, of nutrition labeling for firms that do not now consider it economcially feasible. Ample reasons suggest why a manufacturer using such data bases to support label statements could not be relieved of any further responsibility for the reliability of those statements; they include greater than expected degradation of labile nutrients due to inadequate attention to good handling, storage, and manufacturing practices. Nevertheless, for many foods a well-researched data base could be used with high reliability in conjunction with good manufacturing practices. FDA and USDA would like to encourage the development and use of such data bases where they offer significant cost savings. They are therefore seeking evidence and estimates on the costs of developing scientifically and statistically sound data bases, the identity of the foods and food products that lend themselves to this approach, and the economic advantages such data bases might (or might not) offer over existing approaches to the statement of nutrient content—preferably using specific product examples. The degree of interest food companies, trade associations, and other industry organizations express in such opportunities is, of course, highly relevant to the ultimate decision about their use.

Costs of establishing data bases depend on the amount and reliability of available information, the variability of nutrients naturally occurring in agricultural produce, and the stability of nutrients during processing and storage. The cost of developing data bases could be reduced, for example, by pooling resources within a segment of the food industry to centralize the research and data collection. The sizes of firms and the resources they have will also affect the development of data bases. The agencies are therefore asking that comments address the costs and feasibility of developing industry data bases.

Request for Comments/Notice of Public Hearing

The agencies are providing a 90-day comment period and will hold a public hearing to gather views on their tentative positions and the issues discussed here. Last year's five public hearings and written submissions produce information on what the public wants in the way of improved food labeling; the additional opportunity for comment will give the public a chance to provide views on how the agencies should proceed on the basis of this information. Additional information submitted at this stage is very important, because the decisions it will help shape will establish food labeling policy for the foreseeable future. The agencies therefore welcome comments on their tentative proposals to revise food labels, including their feasibility, their cost and their necessity.

The 1978 food labeling hearings were designed primarily to gather the views of unassociated individuals. At that time, the agencies encouraged others to submit their comments in writing. Having had the opportunity to review and analyze the information thus gathered, the agencies have agreed that an additional public hearing will provide organized consumer groups, state associations, industry, and trade associations—as well as individuals—with an opportunity to testify.

The public hearing will be held before representatives of FDA, USDA, and FTC on March 4 and 5, 1980, beginning both days at 9:30 a.m., in the main auditorium, Department of Commerce, Fourteenth St. and Constitution Ave. NW., Washington, D.C. It will be conducted in accordance with Title 21 of the Code of Federal Regulations, Part 15—Public Hearings Before the Commissioner. For scheduling purposes, we ask those who want to give a presentation to let us know, no later than February 22, 1980, by writing to:

Mr. Gary Dykstra, Regulatory Operations Staff (HFC–22), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3470.

Written comments should be submitted to the Hearing Clerk, Food and Drug Administration (HFA–305), Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857 by March 20, 1980.

Written submissions will also be accepted at the hearing from participants who want additional information included in the record. The submissions should be identified with

the docket number found in the brackets in the heading of this document. These submissions may be seen in the office of the Hearing Clerk, Food and Drug Administration, from 9 a.m. to 4 p.m., Monday through Friday.

Following evaluation of these comments, FDA and USDA will begin to implement food labeling revisions in accordance with their respective authorities and procedures. Those issues that can be resolved through new or revised regulations will be handled by the notice and comment rulemaking process: publication in the Federal Register of a proposal for comment, review of comments, and issuance of a final regulation. Any requests for legislation will be handled through each agency's normal channels; the agencies will coordinate all actions to ensure consistency.

Dated: December 8, 1979.

Jere E. Goyan,

Commissioner of Food and Drugs.

Dated: December 10, 1979.

Carol Tucker Foreman,

Assistant Secretary for Food and Consumer Service, USDA.

Dated: December 17, 1979.

Albert H. Kramer,

Director, Bureau of Consumer Protection, FTC.

[FR Doc. 79-39185 Filed 12-18-79; 10:00 am]

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Federal Register

Vol. 44, No. 247

Friday, December 21, 1979

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The items in this list were editorially compiled as an aid to **Federal Register** users. Inclusion or exclusion from this list has no legal significance. Since this list is intended as a reminder, it does not include effective dates that occur within 14 days of publication.

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Conservation and Solar Energy Office—

66780 11–21–79 / First annual State applications for financial assistance; change in submission date

INTERIOR DEPARTMENT

Surface Mining and Reclamation Enforcement Office—

67057 11–21–79 / Abandoned mine reclamation funds; amendment to regulations

INTERSTATE COMMERCE COMMISSION

66831 11–21–79 / Procedures governing processing, investigation and disposition of overcharge, duplicate payment, or overcollection claims

SECURITIES AND EXCHANGE COMMISSION

67107 12–12–79 / Filing of information required in solicitation of proxies other than by issuer

[Corrected at 44 FR 71821, 12–12–79]

Rules Going Into Effect Monday, December 24, 1979

AGRICULTURE DEPARTMENT

Food Safety and Quality Service—

67067 11–23–79 / Marking of meat food products with official inspection legend and ingredient statement

HEALTH, EDUCATION, AND WELFARE DEPARTMENT

Food and Drug Administration—

36378 6–22–79 / Drugs for human use; over-the-counter (OTC) daytime sedatives

LABOR DEPARTMENT

Occupation Safety and Health Administration—

60980 10–23–79 / Appendices to Standards on occupational exposure to lead

TRANSPORTATION DEPARTMENT

Federal Aviation Administration—

61323 10–25–79 / Updating of certain airworthiness, equipment and operations provisions

Rules Going Into Effect Tuesday, December 25, 1979

SECURITIES AND EXCHANGE COMMISSION

57037 10–3–79 / Oil and gas producers; postponement of audit requirement for reserve information

57030 10–3–79 / Oil and gas producers; supplemental disclosures on the basis of reserve recognition accounting

40688 9–12–78 / Oil and gas producing activities; financial accounting and reporting practices

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Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws.**

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